

# ADVERSE REACTION TRACKING USER MANUAL

Version 4.0

September 2005

Health Data Systems Veterans Health Administration Department of Veterans Affairs

## **Revision History**

<b>Revision Date</b>	Page or	Description	Author
	Chapter		
August	Appendices 1	Updated Reaction and	JoAnn Green
	and 2	Reactant file entries	
April-July 2005	Pgs 10-12,	Updates for GMRA*4.0*23	
	121-134	and data standardization.	
December 2004	Throughout	Edits based on SQA review,	
	manual.	including removal of Marked	
		on Chart prompts.	
November 2004	Pages 1 and	NKA deletion enhancement	
	39	added	
October/November	Throughout	Patient name and SSN and	
2004	manual.	provider name updates to	
		comply with Patient privacy	
		SOP.	
October 2004	Appendix 3	CPRS GUI 25 Release Notes	
		for ART added and updated.	
January 2004	Page 24	Patch 17 (GMRA*4*17) Free	
		Text Allergy Clean Up Utility	
		info added.	

# **Table of Contents**

Introduction	
Orientation	6
Assumptions about the Reader	6
Reference Materials	6
Package Management	8
Package Operation	9
Adverse Reaction Tracking [GMRAMGR]	
Enter/Edit Site Configurable Files	
Free Text Allergy Clean Up Utility	20
Adverse Reaction Tracking User Menu	33
Enter/Edit Patient Reaction Data	
Active Listing of Patient Reactions	39
Edit Chart and ID Band	41
List by Location of Unmarked ID Bands/Charts	
Patient Allergies Not Signed Off	44
List by Location of Undocumented Allergies	45
Print Patient Reaction Data	47
Adverse Reaction Tracking Clinician Menu	49
Enter/Edit Patient Reaction Data	
FDA Enter/Edit Menu (Clinician)	53
Enter/Edit FDA Report Data	54
Enter/Edit P&T Committee Data	
Reports Menu (Clinician)	
Adverse Reaction Tracking Verifier Menu	
Enter/Edit Patient Reaction Data	74
Verify Patient Reaction Data	76
Reports Menu (Verifier)	
FDA Enter/Edit Menu (Verifier)	99
P&T Committee Menu	104
Enter/Edit P&T Committee Data	
Enter/Edit FDA Report Data	
Reports Menu (P&T)	
Using ART in CPRS GUI	
On the Cover Sheet	
Entering Allergies from the Cover Sheet	
Entering No-Known-Allergies Assessments	
Marking Allergies as Entered in Error	
Allergy Detail changes	
Reviewing and Creating Postings	
Entering Allergies from the Orders Tab	
Entering No Known Allergies	
Glossary	
Appendix 1: National GMR Allergies File (120.82) Entries	137
Appendix 2: National Sign/Symptoms (120.83) File Entries	140
Appendix 3: CPRS (GUI 25 and 26) Release Notes – ART	

## Introduction

The objective of ART is to track and report patient allergy and adverse reaction data. This is accomplished through three interfaces:

- 1. ART menus and options within character-based VistA
- 2. Character-based CPRS
- 3. CPRS GUI

#### Recent changes to ART

#### GMRA\*4.0\*23 - HDR/DS Changes

This patch introduces the changes necessary to standardize the data stored in the allergy package. Standardized data is necessary for inclusion in the Health Data Repository (HDR).

In addition, this patch introduces two new cross-references and a new Application Programmer Interface (API) that will allow changes to existing reactant terms to propagate through existing allergy entries in the PATIENT ALLERGIES file (120.8).

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) are being standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs /symptoms.

The data standardization team has reviewed existing local entries at the sites and has added those terms to files 120.82 and 120.83 as appropriate. Requests for new terms will be made via the New Term Rapid Turnaround (NTRT) process. If approved, the new term will be sent to all sites for inclusion in file 120.82 or 120.83. For more information on this process, see

- Data Standardization Project Website: <a href="http://vaww.infoshare.va.gov/Data\_Standardization/default.aspx">http://vaww.infoshare.va.gov/Data\_Standardization/default.aspx</a>
- The NTRT Program website. http://vista.med.va.gov/ntrt/

In addition to the updates to files 120.82 and 120.83, existing active entries in file 120.8 need to be updated to use standard reactants. In a previous allergy patch, a utility was distributed that identified free text entries. The utility also included options that allowed the user to fix these entries by either updating them or marking them as entered in error.

#### **CPRS Changes**

#### **PATCH OR\*3\*233**

**Support for Allergy Synonyms** –Allergy synonyms, if present, are now included in the SIGNS/SYMPTOMS selection box. This is included in patch OR\*3\*233, which will be distributed with GMRA patch 23.

#### **CPRS GUI 26**

- Marking Allergies as Entered in Error Now Controlled by Parameter In CPRS v25, any user could enter new allergies, mark a patient as NKA (no known allergies), and mark allergies entered in error from the cover sheet and the detailed display window. In v.26, the Entered in Error option requires the new parameter OR ALLERGY ENTERED IN ERROR to be enabled for the user. The other options remain open to all users as before.
- Free-Text Signs and Symptoms No Longer Allowed To support of data standardization efforts, developers removed the ability to enter free-text signs/symptoms. Users must now select items from the list of available signs/symptoms.
- Inconsistent Sending of Bulletin for Marked on Chart CPRS always sent the "Marked on Chart" bulletin if the user entered an allergy from the Orders tab. CPRS never sent the bulletin if the user entered the allergy from the Cover Sheet. This inconsistency has been corrected, and CPRS will never send the bulletin when the user enters a new allergy.
- The "Bulletin has been sent" message that CPRS displays after the user requests the addition of a new causative agent now includes the same warning included in the bulletin about that reactant not being added to the patient's record.

#### GMRA\*4.0\*21

Free-text allergies may no longer be entered through CPRS. At sites that have installed OR\*3.0\*195, OR\*3.0\*216, and GMRA\*4.0\*21, CPRS users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file, and allergies do not appear on the Orders tab. Patch OR\*3.0\*216 includes a post-installation routine that changes the status of all active allergy orders to complete and, therefore, removes the allergy orders from the Orders tab.

In addition, users can no longer select OTHER ALLERGY/ADVERSE REACTION as a type of causative agent, nor can they select OTHER REACTION as a type of sign/symptom. Changes to the ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site's *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate—by clicking either its YES or NO button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was YES. In this version, the default button is NO. Furthermore, when users click the system X button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

**NKA:** It is now possible to delete an assessment of NKA from within the ART package.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the "Does this patient have any known allergies or adverse reactions?" prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO. In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Use of ART within CPRS is primarily described in CPRS documentation, but some examples are provided in this manual.

#### **ART Package Components**

The four major components of the ART package are:

- 1. Data Entry Options Adverse Reaction Tracking has two options where a user can enter data.
  - a. Enter/Edit Patient Reaction Data This option allows the clinical users (i.e., doctors, nurses, other clinicians and clerks) to enter data into ART.
  - b. Verify Patient Reaction Data This option allows the verifiers designated by ART to verify the correctness of data entered by the clinical users into ART. This option does NOT perform evaluation of suspected Advanced Drug Reactions (ADR) as described in Section 5.a.(2).(d) of Directive 10-92-070.
- 2. Reporting options These options report the patient causative agent data to you via a print option. Also, this data is made available to other software applications via a data extract utility.
- 3. Enter/Edit Site Configurable Files This menu allows the various site configurable files to be modified to allow ART to better meet the needs of an individual site.
- 4. Adverse Drug Reaction (ADR) options These options support implementation of Directive 10-92-070. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070. This component also generates the reports needed by the FDA.

There are four major users of the software:

- 1. Clinical users These are the doctors, nurses, other clinicians, and clerks entering the data into ART. They are required to enter data pertinent for a particular allergy/adverse reaction. If the allergy/adverse reaction was observed at the site, data pertaining to any possible legal action could be tracked. This data would then be made available to users of any service using the Reporting options, thus avoiding any errors in care. Two other data elements that are tracked are the date/time that the patient chart was marked and the date/time that the patient ID band was marked, indicating the patient's reaction to the particular causative agent. Automated mail bulletins are sent to the appropriate users when the date/time patient chart marked data field has not been recorded.
- 2. Verifiers These are designated users by the site who verify the correctness of the data in ART. The verifiers are designated when the Information Resources Management Service (IRM) allocates the GMRA-ALLERGY VERIFY security key to a user and assigns the ART Verifier Menu. The verifiers may be clinical pharmacists, dietitians, or other clinical personnel. Automated mail bulletins will be sent to the ART verifiers when an allergy/adverse reaction has been entered and signed (completed) by a user. Verification may be important in observed instances of adverse drug reactions where a Quality Assurance (QA) investigation may be conducted. In general, it is a good principle to have someone verify all of the data entered into ART.
- 3. Pharmacy and Therapeutics (P&T) Committee users These users are the members of the hospital's P&T Committee and are assigned the P&T Committee Menu option. They will use the information in ART to review ADRs in the hospital, classify them as significant reactions, and determine whether they are related to particular drugs, and depending on

the severity of the ADR, may report it further to the FDA. A printed copy of the form used to report to the Food and Drug Administration (FDA) can be generated by ART. Automated mail bulletins will be sent to the P&T Committee users when an observed drug reaction is entered into the system.

4. Software developers - These users will use the data extract utility (GMRADPT routine) to gather ART data for display within their specific VistA application.

## Orientation

This section of the manual provides general information about conventions used in this manual and for using the Adverse Reaction Tracking (ART) application. It describes conventions for character-based (roll and scroll and List Manager) interfaces and also for the graphic user interface (GUI), as seen through the Computerized Patient Record System (CPRS).

- Descriptive text is presented in a proportional font (as represented by this font).
- "Snapshots" of computer online displays (i.e., roll-and-scroll screen captures/dialogs) and computer source code are shown in a *non*-proportional font and enclosed within a box.
  - User responses to online prompts are in boldface type.
  - The word "Enter" in snapshots further prompts the user to press the Enter or Return key on their keyboard.
  - Author comments are displayed in italics or as "callout" boxes.

## Assumptions about the Reader

This guide is written with the assumption that readers have experience with the following:

- VistA computing environment
- Kernel Installation and Distribution System [KIDS]
- VA FileMan data structures and terminology

This guide doesn't explain how the overall VistA conventions. Such methods and procedures are documented elsewhere. We suggest you look at the various VA home pages on the World Wide Web (WWW) for a general orientation to VistA. For example, go to the Health System Design & Development (HSD&D) Home Page at the following web address: <a href="http://vista.med.va.gov/">http://vista.med.va.gov/</a>

## **Reference Materials**

Readers who wish to learn more should consult the following:

- Health Data Informatics (HDI) Data Standardization Toolset Installation Guide
- VUID Planning Requirements Document from Enterprise Reference Terminology (ERT): http://tspr.vista.med.va.gov/warboard/ProjectDocs/ERT/VUID%20Server%20plan.doc
- Data Standardization Project Website: http://vaww.infoshare.va.gov/Data Standardization/default.aspx
- The NTRT Program website. This website allows users to submit new terms to be included in the national standard. The website also features a user guide that provides instructions for submitting a new term: <a href="http://vista.med.va.gov/ntrt/">http://vista.med.va.gov/ntrt/</a>
- The VistA documentation library has more detailed information about all aspects of VistA: <a href="http://www.va.gov/vdl/">http://www.va.gov/vdl/</a>

Documentation is made available online, on paper and in Adobe Acrobat Portable Document Format (.PDF). A .PDF must be read using the Adobe Acrobat Reader (i.e., ACROREAD.EXE), which is freely distributed by Adobe Systems Incorporated at the following URL or Web address: <a href="http://www.adobe.com/">http://www.adobe.com/</a>

# **Package Management**

This package does not impose any additional legal requirements on you, nor does it relieve you of any legal requirements. All users are reminded that many of the reports and mail bulletins generated by this package contain confidential patient information, which is protected by the Privacy Act. A basic knowledge of VistA is presumed for most users of the software. The Application Coordinator (ADPAC) should have more than a basic knowledge of VistA and the needs of a clinical environment.

The software does contain two security keys. The GMRA ALLERGY VERIFY key is needed to verify allergy/adverse reactions. The GMRA SUPERVISOR key should be given only to those users who have the authority to override the software's security in order to edit data.

The software itself does not prompt for a user's electronic signature. However, it does contain a programming interface with the Progress Notes package in order to create, edit, and sign progress notes. The Progress Notes software does prompt you for an electronic signature.

The software generates mail bulletins when certain events happen and sends a bulletin to a specified mail group. The mail groups are:

- 1. GMRA MARK CHART A list of users who will need to be notified that the ID Band needs to be updated. The new message reads "The ID band for the following patient needs to indicate that the following Allergy/adverse reaction has been reported"
- 2. GMRA VERIFY DRUG ALLERGY A list of all verifiers who will need to be sent drug reaction information.
- 3. GMRA VERIFY FOOD ALLERGY A list of all verifiers who will need to be sent food reaction information.
- 4. GMRA VERIFY OTHER ALLERGY A list of all verifiers who will need to be sent other types of reaction information (i.e., not drug or food).
- 5. GMRA P&T COMMITTEE FDA A list of the members of the Pharmacy and Therapeutic (P&T) Committee.
- 6. GMRA REQUEST NEW REACTANT When adding a new allergy entry, you are prompted for the reactant. If you cannot find a reactant to match your input, then you are given the option to send an email message requesting that the new reactant be added.

Contact the ADPAC or IRM support staff if you need to be a member of one of these mail groups.

# **Package Operation**

Adverse Reaction Tracking (ART) can be used through CPRS – both the GUI and List manager interfaces, and through GMRA options in character-based VistA. This manual primarily describes the latter use, but also briefly describes the use in CPRS.

Within the character-based VistA, the ART software includes six menus to assist users in tracking and reporting allergy/adverse reaction data:

- 1. Adverse Reaction Tracking [GMRAMGR] This is the top-level menu. It should be given to the package's ADPAC and/or IRM support person.
- 2. Adverse Reaction Tracking User Menu [GMRA USER MENU] This menu can be assigned to clerks who will enter adverse reaction data.
- 3. Adverse Reaction Tracking Clinician Menu [GMRA CLINICIAN MENU] This menu can be assigned to clinicians who will use the package.
- 4. Adverse Reaction Tracking Verifier Menu [GMRA VERIFIER MENU] This menu should be assigned to users who will verify adverse reaction data.
- 5. P&T Committee Menu [GMRA P&T MENU] This menu can be given to Pharmacy and Therapeutic Committee members.

The rest of this chapter describes the menus and options. Also, examples of each option are given.

## Adverse Reaction Tracking [GMRAMGR]

This is the main menu that has all options of the Adverse Reaction Tracking System. This menu should only be given to the ART Applications Coordinator (ADPAC) and/or IRM support personnel.

- 1 Enter/Edit Site Configurable Files ... [GMRA SITE FILE MENU]
- 2 Adverse Reaction Tracking User Menu ... [GMRA USER MENU]
- 3 Adverse Reaction Tracking Clinician Menu ... [GMRA CLINICIAN MENU]
- 4 Adverse Reaction Tracking Verifier Menu ... [GMRA VERIFIER MENU]
- 5 P&T Committee Menu ... [GMRA P&T MENU]

#### **Enter/Edit Site Configurable Files**

This is a menu of the various options that the site can use to tailor ART to better meet its needs. This menu should be used by the ADPAC or IRM Support Staff only.

NOTE: The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) are being standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs/symptoms. The ability to add free text reactants was removed by a previous allergy patch.

The data standardization team has reviewed existing local entries at the sites and has added those terms to files 120.82 and 120.83 as appropriate. Requests for new terms will be made via the New Term Rapid Turnaround (NTRT) process. If approved, the new term will be sent to all sites for inclusion in file 120.82 or 120.83.

The options on this menu are still available, but will not allow entries; this was done to further emphasize the changes to the application.

- 1. Edit Allergy File
- 2. Enter/Edit Signs/Symptoms Data
- 3. Enter/Edit Site Parameters
- 4. Sign/Symptoms List
- 5. Allergies File List
- 6. Free text allergy clean up utility

#### Edit Allergy File Enter/Edit Signs/Symptoms Data

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) are being standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs/symptoms.

#### Enter/Edit Site Parameters

The Enter/Edit Site Parameters [GMRA SITE FILE] option allows site configuration for multiple divisions at the site. The software provides a generic site configuration entry called HOSPITAL. These parameters are stored in the GMR Allergy Site Parameters file (#120.84).

The site can configure the following:

- 1. The list of the ten most common signs/symptoms that you will see.
- 2. The autoverification of data. Autoverification is the process by which the software automatically changes the status of the data to verify when you who entered the data signs off (completes) on it. The site can determine which of the types of reactions are to be autoverified and which are to follow the normal verification procedure. There are three parameters used to autoverify data: Autoverify Food/Drug/Other, Autoverify Observed/Historical, and Autoverify Logical Operator. The verification of data is important. Minimally, all drug reactions will need verification. Depending on the site, food and other allergies may also need to be verified. Users who will verify the data must have the GMRA-ALLERGY VERIFY security key.
- 3. Whether the originator of the data should provide comments.
- 4. Whether the site documents the marking of a patient's ID band or chart to indicate the presence of an allergy/adverse reaction. There are three parameters with regards to this documentation: Mark ID Band Flag Method of Notification, Alert ID Band/Chart Mark, and Send Chart Mark Bulletin for New Admissions.
- 5. FDA reporting data. The site can choose to require you to enter FDA data at the time a reaction is entered. Also, the site may edit the reporter information that will appear on the FDA Adverse Reaction reports.
- 6. Whether to allow comments to be added to the reaction data that is entered in error. This allows you to indicate why the data is incorrect.

#### **Example:**

```
Select Enter/Edit Site Configurable Files Option: 3 Enter/Edit Site Parameters
Select GMR ALLERGY SITE PARAMETERS NAME: ??
HOSPITAL

You may enter a new GMR ALLERGY SITE PARAMETERS, if you wish
This field is the name of this set of parameters. The name of the base
set that is sent out is "HOSPITAL". The code will work more efficiently
if the name of the base set of parameters is not changed from "HOSPITAL"

Select GMR ALLERGY SITE PARAMETERS NAME: HOSPITAL
NAME: HOSPITAL// (No editing)
Select DIVISION: ?
Answer with DIVISION
Choose from:
VAMC ONE
VAMC ONE
```

```
VAMC THREE
       You may enter a new DIVISION, if you wish
Answer with INSTITUTION NAME, or STATUS, or STATION NUMBER, or
    OFFICIAL VA NAME, or CURRENT LOCATION, or CODING SYSTEM/ID PAIR, or
    NAME (CHANGED FROM), or CODING SYSTEM
Do you want the entire INSTITUTION List? N (No)
Select DIVISION: VAMC ONE
The following are the ten most common signs/symptoms:
1. CHILLS
                                 6. DIARRHEA
2. ITCHING, WATERING EYES
                                  7. HIVES
3. HYPOTENSION
                                  8. DRY MOUTH
                                  9. DRY NOSE
4. DROWSINESS
5. NAUSEA, VOMITING
                                 10. RASH
Enter the number of the sign/symptom that you would like to edit: ??
   ENTER THE CORRECT NUMBER (1-10) OF THE SIGN/SYMPTOM TO BE EDITED
Enter the number of the sign/symptom that you would like to edit: 6
REACTION: DIARRHEA// ??
       One of the ten most commonly selected reactions.
  Choose from:
  AGITATION
                 NATIONAL SIGN/SYMPTOM
  AGRANULOCYTOSIS NATIONAL SIGN/SYMPTOM
  ALOPECIA NATIONAL SIGN/SYMPTOM
  ANAPHYLAXIS
                  NATIONAL SIGN/SYMPTOM
  ANEMIA NATIONAL SIGN/SYMPTOM
               NATIONAL SIGN/SYMPTOM
  ANOREXIA
              NATIONAL SIGN/SYMPTOM
  ANXIETY
            NATIONAL SIGN/SYMPTOM
  APNEA
  APPETITE, INCREASED
                           NATIONAL SIGN/SYMPTOM
  ARRHYTHMIA NATIONAL SIGN/SYMPTOM
  ASTHENIA
                NATIONAL SIGN/SYMPTOM
  ASTHMA
              NATIONAL SIGN/SYMPTOM
  ATAXTA
              NATIONAL SIGN/SYMPTOM
  ATHETOSIS
               NATIONAL SIGN/SYMPTOM
  BRACHYCARDIA
                 NATIONAL SIGN/SYMPTOM
  BREAST ENGORGEMENT
                          NATIONAL SIGN/SYMPTOM
  BRONCHOSPASM NATIONAL SIGN/SYMPTOM
  CARDIAC ARREST
                     NATIONAL SIGN/SYMPTOM
  CHEST PAIN
                  NATIONAL SIGN/SYMPTOM
REACTION: DIARRHEA// AGITATION
                                  NATIONAL SIGN/SYMPTOM
The following are the ten most common signs/symptoms:
1. CHILLS
                                 6. AGITATION
2. ITCHING, WATERING EYES
                                  7. HIVES
3. HYPOTENSION
                                 8. DRY MOUTH
                                 9. DRY NOSE
4. DROWSINESS
5. NAUSEA, VOMITING
                                 10. RASH
Enter the number of the sign/symptom that you would like to edit: <Enter>
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// ??
       This field determines which types of allergies a site wants autoverified
       at you sign off.
    Choose from:
             NO AUTOVERIFY
      0
      1
              AUTOVERIFY DRUG ONLY
              AUTOVERIFY FOOD ONLY
```

AUTOVERIFY DRUG/FOOD

```
AUTOVERIFY OTHER ONLY
                AUTOVERIFY DRUG/OTHER
       5
               AUTOVERIFY FOOD/OTHER
               AUTOVERIFY ALL
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// <Enter>
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY// ??
        This field is configurable by the site to allow autoverification of
        observed or historical allergies.
     Choose from:
       0
               NO AUTOVERIFY
       1
               AUTOVERIFY HISTORICAL ONLY
                AUTOVERIFY OBSERVED ONLY
               AUTOVERIFY BOTH
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY//
AUTOVERIFY LOGICAL OPERATOR: OR// ??
        This field will determine how the Autoverify Food/Drug/Other and
        Autoverify Observed/Historical parameters relate to each other. OR means
        that the reaction will be autoverified if it meets the criteria of one of
        the two parameters, while AND means the reaction will be autoverified only
        if it meets the criteria of both parameters. If this field is left null,
        the OR condition will be used.
        For example, if you want to verify only observed drug reactions, you would
        set the Autoverify Food/Drug/Other parameter to AUTOVERIFY FOOD/OTHER
        and the Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY, and the
        Autoverify Logical Operator to OR. This means that a reaction that has
        a type of Food/Other OR is Historical will be autoverified, thus leaving
        observed drug reactions to be verified.
       Another example would be if you wanted to verify all observed reactions
       and all drug reactions whether observed or historical. The parameters
        should be set accordingly: Autoverify Food/Drug/Other to AUTOVERIFY
       FOOD/OTHER, Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY and
       Autoverify Logical Operator to AND. In this case to be autoverified, a
        reaction has to have a type of Food/Other AND it must be Historical, all
        other reactions will need to be verified.
     Choose from:
      !
               AND
AUTOVERIFY LOGICAL OPERATOR: OR// <Enter>
REQUIRE ORIGINATOR COMMENTS: NO// ??
        This field indicates whether the originator will be required to enter
        comments for an OBSERVED reaction.
     Choose from:
               YES
REQUIRE ORIGINATOR COMMENTS: NO// <Enter>
MARK ID BAND FLAG: YES// ??
        This field is an indicator to denote whether the site wants
        to document if the patient ID band should be marked for
        a certain allergy.
        The system will assume the site wants to document the marking of inpatient
        ID bands. If this field is answered NO, the site does not want to
        document the marking of inpatient ID bands.
     Choose from:
       0
               NO
       1
                YES
MARK ID BAND FLAG: YES// <Enter>
METHOD OF NOTIFICATION: BULLETIN// ??
```

```
This field tells ART if or how users should be notified for chart
        or ID band markings. There are three methods. The first method is the
        use of BULLETINs, which is the current way ART works. The
        second method is the use of OE/RR Teams. If this method is used, then
        you will need to set up different teams for each ward and also assign
        printers to these teams. The third method is to turn off the function.
     Choose from:
       Ω
               BULLETIN
       1
                OE/RR TEAMS
               NO NOTIFICATION
METHOD OF NOTIFICATION: BULLETIN// <Enter>
ALERT ID BAND/CHART MARK: YES// ??
        This field is to let the system know if you want to issue alerts
        if the fields have not been answered in the Enter/Edit Patient Reaction
        Data portion of the system. If the field is answered yes(1) or is null
        then, the system will continue to issue the alerts. If this field is
        no(0), then the system will not issue alerts for this record.
     Choose from:
      1
       Ω
               NO
ALERT ID BAND/CHART MARK: YES// <Enter>
SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// ??
        This is to indicate if the site wants to send chart mark bulletin
        for a new admission.
     Choose from:
       1
                YES
       Λ
                NO
SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// <Enter>
FDA DATA REQUIRED: YES// ??
        This field will indicate whether the entry of FDA Data should be required
        during the Enter/Edit Patient Reaction Data. If this field is answered "YES",
        then you must enter the FDA Data at the time of entering a reaction.
        If this field is left null or answered "NO", then the FDA Data entry will
        not be required during the Enter/Edit Patient Reaction Data option.
     Choose from:
               YES
      У
               NO
FDA DATA REQUIRED: YES// <Enter>
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
        Permit users to indicate why a reaction was Entered in Error.
     Choose from:
      1
               YES
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
        // <Enter>
REPORTER NAME:
     ADDRESS:
        CITY:
        STATE:
          ZIP:
        PHONE:
  OCCUPATION:
Do you want to edit Reporter Information shown above? No// <Enter> (No)
         Edit Allergy File
         Enter/Edit Signs/Symptoms Data
```

```
3 Enter/Edit Site Parameters
4 Sign/Symptoms List
5 Allergies File List
6 Free text allergy clean up utility

You have PENDING ALERTS
Enter "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option:
```

NOTE: These "Reporter" data fields contain the site's default values that will appear on the FDA adverse reaction reports. This information may be left blank. You will be prompted for the reporter information when creating an FDA report.

#### Sign/Symptoms List

This option lets you print a list of entries in the Sign/Symptoms file (#120.83). You may print all entries by accepting the default value (FIRST) at the "Name" prompt or may select a subset of entries. The listing includes the name of the sign/symptom, whether it is a nationally distributed entry or a locally created entry, and any of its synonyms. This option is meant to be a useful tool for ADPACs in maintaining the Sign/Symptoms file.

#### Example:

Select Enter/Edit Site Con:	figurable Files Option: 4 Sign/Symptoms List
START WITH NAME: FIRST// <	
DEVICE: (Enter a printer na	ame for a hard copy or <enter> to bring the</enter>
output to your screen)	
SIGN/SYMPTOMS LIST	JUN 8,2004 09:23 PAGE 1
NAME	Nat'l/Local SYNONYM
ACTEVETON	National
AGITATION AGRANULOCYTOSIS	National National
ALOPECIA	National
ANAPHYLAXIS	National
ANEMIA	National
ANOREXIA	National
ANXIETY	National ANX
APNEA	National ANA
APPETITE, INCREASED	National
ARRHYTHMIA	National
ASTHENIA	National
ASTHENIA	National
ATAXIA	National
ATHETOSIS	National
BRACHYCARDIA	National
BREAST ENGORGEMENT	National
BRONCHOSPASM	National
CARDIAC ARREST	National
CHEST PAIN	National
CHILLS	National
COMA	National
CONFUSION	National
CONGESTION, NASAL	National
CONJUNCTIVAL CONGESTION	National
CONSTIPATION	National
COUGHING	National
DEAFNESS	National
DELERIUM	National
DELUSION	National
DEPRESSION	National
DEPRESSION, MENTAL	National
DEPRESSION, POSTICTAL	National

#### Allergies File List

This option prints a captioned list of all entries in the GMR Allergies file (#120.82). The list is sorted alphabetically by NAME. You may list all entries by accepting the default answer (FIRST) to the "start with" prompt or may select a subset to print. The list contains the allergy name, type, whether it is a nationally distributed entry, synonyms, if any, VA Drug Class, if applicable, and drug ingredients, if applicable. This option is meant to be a helpful tool for maintaining the GMR Allergies file.

#### Example

Select Enter/Edit Site Configurable Files Option: 5 Allergies File List START WITH NAME: FIRST// <ret> DEVICE: (Enter a printer name for a hard copy or <ret> to bring the output to your screen) GMR ALLERGIES LIST JUN 8,2004 09:20 PAGE 1 NAME: ADHESIVE TAPE ALLERGY TYPE: OTHER NATIONAL ALLERGY: NATIONAL ALLERGY NAME: ALCOHOL ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY DRUG INGREDIENT: ALCOHOL NAME: ANIMAL HAIR ALLERGY TYPE: OTHER NATIONAL ALLERGY: NATIONAL ALLERGY NAME: ANISE OIL ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY DRUG INGREDIENT: ANISE OIL NAME: ANTIRABIES SERUM ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY VA DRUG CLASSES: IM400 DRUG INGREDIENT: ANTIRABIES SERUM NAME: ASCORBIC ACID ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY VA DRUG CLASSES: VT400 DRUG INGREDIENT: ASCORBIC ACID NAME: ASPARTAME ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY SYNONYM: NUTRA SWEET DRUG INGREDIENT: ASPARTAME NAME: ASPIRIN ALLERGY TYPE: DRUG, FOOD NATIONAL ALLERGY: NATIONAL ALLERGY VA DRUG CLASSES: MS101 DRUG INGREDIENT: ASPIRIN

#### Free Text Allergy Clean Up Utility

This option was distributed with Patch GMRA\*4.0\*17 to help sites identify and fix allergy entries that have free-text reactants.

After installing this patch, free-text entries are no longer allowed from within the ART package. A subsequent patch (OR\*3\*216) to CPRS prevents free-text entries from within CPRS as well.

Lower-case entries are also no longer allowed. Previously, lower-case entries could be added to the GMR ALLERGIES file (120.82). A patch 17 post-installation routine identified any local entries and updated the entries to upper case. Synonyms were also be checked and converted to upper case, if required.

A new mail group, GMRA REQUEST NEW REACTANT, was added with this patch. Sites should populate this mail group with the people responsible for addressing requests to add new reactants. If users attempt to enter a reactant that is not found during the look-up process, they are asked if they would like to send an email requesting the addition of the new reactant. The request can then be reviewed for accuracy and new local entries can be added, if appropriate. Previously, users were asked if they wanted to add the new entry and it was immediately available in the patient's record. Under the new system, the new reactant must be reviewed before it is added to the patient's record.

When you start the utility, a list of currently existing free-text entries is displayed in alphabetical order. This list may take a few minutes to generate, as all existing entries need to be evaluated to determine which ones are "free text." The list shows the name of the reactant and the number of entries for that reactant. In most cases, they will be unique, but there will be some that have many entries (such as an entry for NO KNOWN ALLERGIES).

When entering the utility, any users who are currently working in the utility are listed. If users are listed as working with the utility, you will not be allowed to update the list. You can only update the list when nobody else is working in the utility.

Once the list is displayed, you can do three things:

- 1. Mark the entry as entered in error
- 2. Update it so that it points to an existing reactant (hopefully, the one that it should have been pointed to originally).
- 3. Add new reactants to the GMR ALLERGIES file (120.82) as local entries, if they are not found in any existing files.

Select OPTION NAME:  $\mathbf{GMRA}$  SITE FILE  $\mathbf{MENU}$  Enter/Edit Site Configurable Files  $\mathbf{menu}$ 

- 1 Edit Allergy File
- 2 Enter/Edit Signs/Symptoms Data
- 3 Enter/Edit Site Parameters
- 4 Sign/Symptoms List
- 5 Allergies File List
- 6 Free text allergy clean up utility

You have PENDING ALERTS

Enter "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option: 6
Free text allergy clean up utility

NOTE: When you start the utility, you may see 3 different things: 1) If the list has never been built, you'll see the message below (building list...), 2) If the list has been previously built and nobody is using the utility, you'll see a message indicating the last time the list was built and you will be asked if you'd like to rebuild the list, 3) If the list is currently being built, you'll get a message indicating that you must wait. Most times a user will see the message in number 2.

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update Oct 27, 2003@08:17:58 Page: 1 of 1

Allergy Tracking Free Text Entries

	2237 1200111113 1200 10110 211012	
	Reactant	# Active Entries
1	CEFAZOLIN SOD 1GM INJ	1
2	Diabetes Mellitus Type II	1
4	Penicillin	1
5	WATERMELON	3
l		

#### Select one or more entries

AE Add/Edit Allergy File EE Mark entered in error DD Detailed Display UR Update to new reactant Select Item(s): Quit// ??

AE - Local site addition and modification functions are no longer available.

Use EE to mark all entries within the selected group as entered in error. You may select multiple groups if you like.

Use DD to get a detailed display. It's highly recommended that you use the detailed display menu to make all changes.

Use UR to update the reactant. Extreme caution should be used when doing mass updates. It would be better to do the updates from within the detailed display menu.

Press enter to continue:

#### **Detailed Display**

The detailed display window shows the patient name and the list of currently active allergies, separated by a tilde (~). This way, you can quickly look and see if the patient already has an active allergy that is the same as the free-text entry. In this case, you would mark it as entered in error.

The "free text detailed display" action lets you see a FileMan inquiry-style listing of the free text entry for selected patient(s). You'll now be able to see the comments, reactions, and other associated information for the free text entry that you're fixing.

When doing a group update or selecting multiple patients for updating from the detailed display listing, the reactant you select for the first patient in the list will become the default for the remaining patients. The exception to that would be if you decide to not accept the default while updating one of the patients. In that case, the last chosen reactant will become the default for the next patient. The default only holds while working with a particular group. Once you select a new reactant group or a new group of patients, you must re-select the reactant. This should cut down on the amount of time needed in selecting the reactant for each patient.

- 1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
- 2. Select the number of a reactant first, and then select DD to see details about the reactant. (Alternatively, you can select the action, DD, and then select the number of the reactant.)

NOTE: For detailed display, you can only select one group at a time.

GMRA SITE FILE MENU Enter/Edit Site Configurable Files menu Edit Allergy File Enter/Edit Signs/Symptoms Data Enter/Edit Site Parameters Sign/Symptoms List 5 Allergies File List Free text allergy clean up utility 6 You have PENDING ALERTS Enter "VA to jump to VIEW ALERTS option Select Enter/Edit Site Configurable Files Option: 6 Free text allergy clean up utility Building list of free text allergies...this may take a few minutes Allergy Tracking Update Oct 24, 2003@15:09:28 Page: 1 of Allergy Tracking Free Text Entries Reactant # Active Entries 1 COCA COLA SYRUP 80Z 1 Diabetes Mellitus Type II 1 NO ALLERGIES 3 1 NO KNOWN ALLERGIES 1 5 Penicillin 1 6 PIZZA 1 7 POLLEN ANTIGEN MIX + Select one or more entries AE Add/Edit Allergy File EE Mark entered in error DD Detailed Display UR Update to new reactant Select Item(s): Next Screen// 3

All	ergy Tracking Update	Oct 24, 2003@15:09:28 Pa	age:	1 of	1
All	ergy Tracking Free Text E	tries			
	Reactant	# Active Entries			
1	COCA COLA SYRUP 80Z	1			
2	Diabetes Mellitus Type I	1			
3	NO ALLERGIES	1			
4	NO KNOWN ALLERGIES	1			
5	Penicillin	1			
6	PIZZA	1			
7	POLLEN ANTIGEN MIX	1			
+	Select one or mo	re entries			
ΑE	Add/Edit Allergy File EE	Mark entered in error			
DD	Detailed Display UR	Update to new reactant			
Sel	ect Item(s): Next Screen/	DD Detailed Display			

Reactant Detailed Display Oct 24, 2003@15:09:28 Page: 1 of

Patient listing for reactant CEFAZOLIN SOD 1GM INJ

Patient Name Last 4

1 ARTPATIENT, ONE 0111

Allergies: PENICILLIN VK ORAL SOLUTION~AMIKACIN~PEANUT OIL~CORTISONE~NUTS~DUST~ STRAWBERRIES~CHICKEN~CHOCOLATE~PHENOL~HAYFEBROL SF~ASA~BILE SALTS~

BILBERRY EXTRACT~POLLEN~POLLEN ALLERGENIC EXTRACT~

ANTIHEMOPHILIC FACTOR, HUMAN~CEFAZOLIN SOD 1GM INJ~SHELL FISH~

RANITIDINE

#### Select a patient

EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Free Text Detailed Display

AE Add/Edit Allergy File

Select Item(s): Quit// DD Free Text Detailed Display

Select Entries from list: 1

PATIENT: ARTPATIENT, ONE REACTANT: CEFAZOLIN SOD 1GM INJ

GMR ALLERGY: OTHER ALLERGY/ADVERSE REACTION ORIGINATION DATE/TIME: OCT 02, 2003@14:02

ORIGINATOR: ARTPROVIDER, ONE OBSERVED/HISTORICAL: HISTORICAL

ORIGINATOR SIGN OFF: YES NATURE OF REACTION: UNKNOWN

VERIFIED: NO ALLERGY TYPE: DRUG

Press return to continue or '^' to stop: <Enter>

#### **Mark Entered in Error**

You can mark an entire group as entered in error from this opening screen. Upon marking the reaction as entered in error, a check is made to see if there are still active reactions for the patient. If there are not any, then you are prompted to enter an updated assessment for the patient.

- 1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
- 2. Select the number of the reactant(s) you wish to mark as entered in error. (Alternatively, you can select the action, Mark Entered in Error, and then select the number of the reactant(s).)

```
Select Enter/Edit Site Configurable Files Option: 6 Free text allergy clean up
utility
Building list of free text allergies...this may take a few minutes
Allergy Tracking Update Sep 19, 2003@11:18:04
                                                                    1 of
                                                           Page:
Allergy Tracking Free Text Entries
   Reactant
                                            # Active Entries
   COCA COLA SYRUP 80Z
1
                                                  1
2
   COLD AIR
                                                  1
3
   Diabetes Mellitus Type II
                                                  1
   DOG HAIR
5
   DONUTS
                                                  1
6
   DOUGH
                                                  1
7
   DR P'S SNAKE OIL ELIXIR
                                                  1
8
   DRUGS
                                                  1
9
   ETETO
                                                  1
10 ENCAINIDE 25MG
           Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Ouit// 5
```

**3.** Type EE for Mark entered in error, and then answer Yes to confirm that you want to mark ALL allergies as entered in error.

```
Select Item(s): Next Screen// EE Mark entered in error

You are about to mark ALL allergies with the selected reactant as entered in error.

ARE YOU SURE? NO// Yes
```

#### **Update to New Reactant**

You may select and update groups of entries from the opening menu; however, it is recommended that you use the detailed display option to review entries in a group before doing a mass update. *Changes cannot be undone!* When the entry is updated, a comment is stored in the PATIENT ALLERGY file indicating who made the change, date/time of change, and a comment that indicates what the previous value was and what the new value is. In addition, the new reactant is compared against current orders and order checking information is returned, if appropriate. When a new reactant is selected, checks are made for duplicate entries and previously entered-in-error information.

NOTE: Due to the way the order checking software works, you may get "false positives." In other words, if the patient currently has an allergy order check for some other order not related to this new reactant, you may still see the order check.

Finally, the drug ingredient/drug class information is updated, if appropriate.

- 1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
- 2. Select a reactant number and then select the action DD.

```
Select Enter/Edit Site Configurable Files Option: 6 Free text allergy clean up
utility
Building list of free text allergies...this may take a few minutes
                             Oct 27, 2003@08:35:56
Allergy Tracking Update
                                                            Page:
                                                                     1 of
Allergy Tracking Free Text Entries
                                            # Active Entries
   Reactant
    CEFAZOLIN SOD 1GM INJ
                                                  1
   Diabetes Mellitus Type II
                                                  1
2
3
   NO ALLERGIES
                                                  1
4
   NO KNOWN ALLERGIES
                                                  1
5
   Penicillin
                                                  1
   WATERMELON
          Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Quit// 6
```

Allergy Tracking Update	Oct 27, 2003@08:36:38	Page:	1 of	1
Allergy Tracking Free Text E	Intries			
Reactant	# Active En	tries		
1 CEFAZOLIN SOD 1GM INJ	1			
2 Diabetes Mellitus Type I	I 1			
3 NO ALLERGIES	1			
4 NO KNOWN ALLERGIES	1			
5 Penicillin	1			
6 WATERMELON	3			
+ Select one or more				
AE Add/Edit Allergy File EE	Mark entered in error			
± ±	Update to new reactant			
Select Item(s): Quit// <b>dd</b>	Detailed Display			
<del></del>				
Reactant Detailed Display	Oct 27, 2003@08:25:50	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant	Oct 27, 2003@08:25:50 : WATERMELON	Page:	1 of	<u>1</u>
Reactant Detailed Display Patient listing for reactant Patient Name	Oct 27, 2003@08:25:50 WATERMELON Last 4	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name ARTPATIENT, ONE	Oct 27, 2003@08:25:50 : WATERMELON	Page:	1 of	<u>1</u>
Reactant Detailed Display Patient listing for reactant Patient Name 1 ARTPATIENT,ONE Allergies: WATERMELON	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name 1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO	Oct 27, 2003@08:25:50 WATERMELON Last 4	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name 1 ARTPATIENT,ONE Allergies: WATERMELON	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name 1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name ARTPATIENT, ONE Allergies: WATERMELON ARTPATIENT, TWO Allergies: WATERMELON	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111 0222 0333	Page:	1 of	1
Reactant Detailed Display Patient listing for reactant Patient Name  1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO Allergies: WATERMELON 3 ARTPATIENT, THREE Allergies: ASPIRIN~WATERMELO	Oct 27, 2003@08:25:50  E WATERMELON Last 4 0111 0222 0333	Page:	1 of	<u>1</u>
Reactant Detailed Display Patient listing for reactant Patient Name  1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO Allergies: WATERMELON 3 ARTPATIENT, THREE Allergies: ASPIRIN~WATERMELO	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111 0222 0333  ON			1
Reactant Detailed Display Patient listing for reactant Patient Name  1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO Allergies: WATERMELON 3 ARTPATIENT, THREE Allergies: ASPIRIN~WATERMELO	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111 0222 0333  ON entries PR Add/Edit Pat	ient Reactic	on	1
Reactant Detailed Display Patient listing for reactant Patient Name  1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO Allergies: WATERMELON 3 ARTPATIENT, THREE Allergies: ASPIRIN~WATERMELO  + Select one or more EE Entered in Error UR Update to new reactant	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111 0222 0333  ON	ient Reactic	on	1
Reactant Detailed Display Patient listing for reactant Patient Name  1 ARTPATIENT, ONE Allergies: WATERMELON 2 ARTPATIENT, TWO Allergies: WATERMELON 3 ARTPATIENT, THREE Allergies: ASPIRIN~WATERMELO  + Select one or more EE Entered in Error	Oct 27, 2003@08:25:50  WATERMELON Last 4 0111 0222 0333  ON entries PR Add/Edit Pat	ient Reactic	on	1

**3.** Select an item # in the Detailed Display, then select UR for Update to New Reactant.

Reactant Detailed Display	Oct 27, 2003@0	08:40:29	Page:	1 of	1
Patient listing for reactant	WATERMELON				
Patient Name	Last 4				
1 ARTPATIENT, ONE	0111				
Allergies: WATERMELON					
2 ARTPATIENT, TWO	0222				
Allergies: WATERMELON					
3 ARTPATIENT, THREE	XXXX				
Allergies: ASPIRIN~WATERMELO	N				
Select a patient					>>>
EE Entered in Error		Add/Edit Patient			
UR Update to new reactant	DD	Free Text Detail	ed Displa	ıλ	
AE Add/Edit Allergy File	_				
Select Item(s): Quit// <b>ur</b>	Update to new re	eactant			
You are about to update the	-	:'S			
WATERMELON allergy to a new	reactant.				
ADE VOIL GIDES NO / WEG					
ARE YOU SURE? NO// YES					
For patient ARTPATIENT,ONE					
Enter Causative Agent: <b>ONION</b>					
Enter Causactive Agenc. ONION					
Checking GMR ALLERGIES (#120	82) file for ma	atches			
Checking one Addenois (#120	.02, 1110 101 110	icciicb			
Now checking INGREDIENT (#50	.416) file for m	natches			

EXTRACT

...OK? Yes//**<ENTER>** (Yes)

You selected ONION EXTRACT Is this correct? Y// <ENTER> ES

Performing order checking...No problems found

Press enter to continue: <ENTER>

Reactant Detailed Display Oct 27, 2003@08:44:13 Page: 1 of 1

Patient listing for reactant WATERMELON

Patient Name Last 4 1 ARTPATIENT, ONE 0111

Allergies: WATERMELON

2 ARTPATIENT, TWO 0222

Allergies: ASPIRIN~WATERMELON

Select a patient >>>

EE Entered in Error PR Add/Edit Patient Reaction UR Update to new reactant AE Add/Edit Allergy File DD Free Text Detailed Display

Select Item(s): Quit//

#### **Add/Edit Patient Reaction**

The addition of local reactants and sign/symptoms is no longer allowed. Requests for new terms/concepts should be made through the New Term Rapid Turn-around (NTRT) process.

Reactant Detailed Display Sep 19, 2003@13:05:28 Page: 1 of 1
Patient listing for reactant DIABETES MELLITUS TYPE II
Patient Name Last 4

1 ARTPATIENT,ONE 0111
Allergies: AMOXICILLIN~ASPIRIN~MILK~ERYTHROMYCIN~CHROMA-PAK INJECTION~Diabetes Mellitus Type II~PENICILLINS

#### Select a patient

EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Free Text Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// PR Add/Edit Patient Reaction

In support of national standardization of the contents of this file, local site addition and modification functions are no longer available.

If you wish to request a new term or modify an existing term, please refer to the New Term Rapid Turnaround (NTRT) web site located at http://vista.med.va.gov/ntrt/. If you have any questions regarding this new term request process, please contact the ERT NTRT Coordinator via e-mail at VHA OI SDD HDS NTRT.

Press enter to continue: <Enter>

### Add/Edit Allergy File

The addition of local reactants and sign/symptoms is no longer allowed. Requests for new terms/concepts should be made through the New Term Rapid Turn-around (NTRT) process.

#### Signing off on Allergies

Before patch 17, the allergy tracking package allowed users to leave entries in a "not signed off" state. Although not complete, the allergy became part of the patient's record, even though you were told that it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient's record.

A change has been made so that no new entry can be left in a "not signed off" state. Upon entering a new allergy, if you enters an "^" at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, you will be asked if the entry is okay. If you enter no, then they'll be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting this process. As a result, no new entries will be allowed to be in an unsigned state.

**NOTE**: Sites should run the "Patient Allergies Not Signed Off" option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered-in-error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient's chart. You are not required to update these entries as data may not be available but you should review them and take action if possible. The post-installation routine will also list any allergies that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

```
GMRA CLINICIAN MENU
                        Adverse Reaction Tracking Clinician Menu
          Enter/Edit Patient Reaction Data
          FDA Enter/Edit Menu ...
   2
   3
          Reports Menu ...
   4
          Edit Chart and ID Band
   5
          Online Reference Card
You have PENDING ALERTS
          Enter "VA to jump to VIEW ALERTS option
Select Adverse Reaction Tracking Clinician Menu Option: 3 Reports Menu
          Active Listing of Patient Reactions
   2.
         Print Patient Reaction Data
   3
         Print an FDA Report for a Patient
   4
         List by Location of Unmarked ID Bands/Charts
   5
         Patient Allergies Not Signed Off
         List by Location of Undocumented Allergies
   7
          List by Location Not Verified Reactions
   8
          List by Location and Date All Signed Reactions
         List FDA Data by Report Date
You have PENDING ALERTS
          Enter "VA to jump to VIEW ALERTS option
Select Reports Menu Option: 5 Patient Allergies Not Signed Off
DEVICE: HOME//
                ANYWHERE
```

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF Run Date/Time: 9/30/03 12:12:09 pm				
ORIGINATOR	PATIENT	ALLERGY	ORIGINATION DATE/TIME	
NO DATA FOR THIS REPORT Enter RETURN to continue or '^' to exit:				

**NOTE:** With GMRA\*4.0\*21, it is now possible to delete an assessment of NKA from within the ART package.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the "Does this patient have any known allergies or adverse reactions?" prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

# Adverse Reaction Tracking User Menu

This menu is assigned to all users of Adverse Reaction Tracking who are not clinicians, verifiers, or ADP coordinators. The options on this menu allow you to enter, edit, and display allergy/adverse reaction data.

- 1. Enter/Edit Patient Reaction Data
- 2. Active Listing of Patient Reactions
- 3. Edit Chart and ID Band
- 4. List by Location of Unmarked ID Bands/Charts
- 5. Patient Allergies Not Signed Off
- 6. List by Location of Undocumented Allergies
- 7. Print Patient Reaction Data
- 8 Online Reference Card

# **Enter/Edit Patient Reaction Data**

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's ID band is marked for this reaction.

### **Selecting a Patient:**

You may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

### Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database, you are asked the above question. A Yes response will allow you to make an entry. A No response will take you back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

### **Selecting a Causative Agent:**

The lookup procedure that is performed when you enter a causative agent deserves a detailed explanation.

- 1) If the causative agent exists as an entry for the patient, then you have the opportunity to edit the data concerning that entry.
- 2) If your response is not part of that patient's entry or you do not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using six files of choices, which are searched in the following order:
  - 1. GMR Allergies (#120.82) this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,
  - 2. National Drug (#50.6) this file contains the names of available drug products including trade names and manufacturer, and
  - 3. National Drug File Trade Names (#50.67)
  - 4. Drug (#50) this file contains the names of drugs that can be used to fill a prescription.
  - 5. Drug Ingredients (#50.416) this file contains the names of individual generic drugs which are components of various drug products,
  - 6. VA Drug Class (#50.605) this file contains the names of the various drug classes used within the Department,

3) If your reactant is not found after Steps 1 and 2, then you are asked "Would you like to send an email requesting (the reactant) be added as a causative agent?" If you answer NO you will return to the reactant lookup; if you answer yes, you see the message "You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may want to add things like sign/symptoms, observed or historical, etc that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit: "If enter is pressed, then the user is allowed to enter comments, and when the comments are saved, the user gets the message "Message sent - NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES//" If the user answers YES, they return to the reactant lookup prompt; if they answer NO, they return to the patient lookup prompt. A mail message is generated to the User making the request and to the Mail Group GMRA REQUEST NEW REACTANT containing the comment entered, the user and contact information, patient, and the reactant.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

NOTE: When selecting entries from the Drug file (#50) you may see the various dosages associated with the drugs. You only need to pick one of these dose forms. The software will figure out which ingredients from that drug the patient had a reaction to and set that information into the database automatically.

#### **Observed vs. Historical Reaction:**

An observed reaction is an event that actually happened to the patient during the patient's stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed you will be asked to enter the observation date. The time of day may be entered, but it is optional.

#### **Observed Report:**

For an observed reaction, you are asked for additional information. You may enter the name of the person who observed the reaction (the default response is the name of you entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, you may edit the date and time of the observation. You will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

### Signs/Symptoms:

A sign/symptom is an effect of the reaction on the patient (e.g., itching). The software comes with a list of nationally recognized signs/symptoms. The site can add additional signs/symptoms to the list. The software displays to you a list of commonly reported signs/symptoms to choose from. You may choose from this abbreviated list or from the full list of choices. You may select as many signs/symptoms as applicable. The site may customize the abbreviated list you see to meet its needs. Observed reactions require you to enter signs/symptoms. A historical reaction allows,

but does not require you to enter signs/symptoms.

Free text sign/symptoms are allowed.

Also, you are asked to enter the date the sign/symptom appeared. The time of day may be entered, but it is optional.

#### Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter. You will only see these prompts if he/she has the GMRA-ALLERGY

NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

#### **Comments:**

The site can determine whether comments from the originator of the entry are required, by setting a software parameter. If that site parameter is set to YES, you are required to enter comments concerning the entry. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and whether they were entered by the originator of the entry, a verifier, or a person who marked the entry as entered in error.

### FDA Data:

When the type of the causative agent is a drug, you may enter further information about the reaction, which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if you will be required to enter FDA data by setting a software parameter. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

#### **Verification of Data:**

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some, or all entries. Conversely, sites may wish to have their users verify none, some, or all entries. If the entry must be verified by a user and the user has the verification key, GMRAALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

### **Generating Progress Notes:**

The ART software has an interface to the TIU package. A progress note will be generated when you verify or enter an observed drug reaction, or mark an entry as entered in error. Also, you may print the note. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

### **Signing Off on an Entry:**

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it.

Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

```
Select Adverse Reaction Tracking User Menu Option: 1 Enter/Edit Patient
Reaction Data
Select PATIENT NAME: ARTPATIENT, ONE 04-01-23 666110111 SC VETERAN
OBS/REACTANT
                                              VER.
                                                    MECH.
                                                            HIST
                                                                  TYPE
ASPIRIN
                                              AUTO ALLERGY HIST
                                                                  DRUG
  Reactions: CHILLS, DRY MOUTH, CHEST PAIN
DILANTIN
                                              YES
                                                    ALLERGY OBS
                                                                  DRUG
 (PHENYTOIN)
  Reactions: DROWSINESS
IBUPROFEN
                                               NO
                                                     UNKNOWN OBS
                                                                   DRUG
                                               YES
                                                     UNKNOWN OBS
                                                                   DRUG
 PENICILLIN
  Reactions: HIVES, DROWSINESS
PHENOBARBITAL
                                               YES
                                                     ALLERGY OBS
                                                                   DRUG
  Reactions: DEPRESSION
                                               YES
                                                     PHARM OBS
                                                                   DRUG
TETRACYCLINE
  Reactions: DROWSINESS
Enter Causative Agent: CHEESE
Checking existing PATIENT ALLERGIES (#120.8) file for matches...
Now checking GMR ALLERGIES (#120.82) file for matches...
   CHEESE
           OK? Yes//
                        (Yes)
(O) bserved or (H) istorical Allergy/Adverse Reaction: O OBSERVED
Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004)
                                                                        DEC
2004 (DEC 06, 2004)
 Are you adding 'DEC 06, 2004' as
   a new ADVERSE REACTION REPORTING? No// y (Yes)
No signs/symptoms have been specified. Please add some now.
The following are the top ten most common signs/symptoms:
1. CHILLS
                                    7. HIVES
 2. ITCHING, WATERING EYES
                                    8. DRY MOUTH
3. HYPOTENSION
                                   9. DRY NOSE
4. DROWSINESS
                                   10. RASH
5. NAUSEA, VOMITING
                                   11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004// (DEC 06,
2004)
The following is the list of reported signs/symptoms for this reaction:
```

```
Signs/Symptoms
                                                   Date Observed
 1 RASH
                                                    Dec 06, 2004
Select Action (A)DD, (D)ELETE OR <RET>:
COMMENTS:
Complete the observed reaction report? Yes// (Yes)
DATE/TIME OF EVENT: DEC 6,2004//
OBSERVER: CPRSPROVIDER, EIGHT
                                       Chief Medical Officer
SEVERITY: m
    1 MILD
    2
       MODERATE
Choose 1-2: 1 MILD
DATE MD NOTIFIED: Dec 6,2004// (DEC 06, 2004)
Enter another Causative Agent? YES// n NO
                             Dec 06, 2004@14:02:53
Causative Agent Data edited this Session:
ADVERSE REACTION
 CHEESE
          Obs/Hist: OBSERVED
           Obs d/t: Dec 06, 2004
    Signs/Symptoms: RASH (12/6/04)Is this correct? NO// y YES
```

# **Active Listing of Patient Reactions**

This option will give a brief listing of the active (i.e., data that is signed off and not entered in error) allergy/adverse reaction data for a selected patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select PATIENT: ARTPATIENT, ONE 04-01-23 666110111		/E DUTY
Enrollment Priority: Category: IN PROCESS	End Date:	
DEVICE: HOME// ;;999 ANYWHERE		
ACTIVE ALLERGY/ADVERSE REACTION LIS	STING	
Run Date/Time: 6/25/04 11:56:58 a	am	
ARTPATIENT, ONE 666-11-0000 FEB 22	2,1942 (62)	
· ·	,	
		OBS/
ADVERSE REACTION	VERIFIED	
TYPE: DRUG		
========		
ALLENT	YES	HIST
ALUMINUM ACETATE	YES	HIST
Reactions: CHILLS (Nov 25, 2002)	1110	11151
AMOXICILLIN	NO	HIST
AMPICILLIN	NO NO	HIST
BILBERRY	YES	
CANDESARTAN	YES	
CARAMEL	YES	HIST
	IES	нтот
Reactions: HIVES (Jan 22, 1998),		
ITCHING, WATERING EYES (Jan 22, 1998)	TTD C	ODG
CORICIDIN TAB	YES	OBS
Reactions: CHILLS, HYPOTENSION, NAUSEA, VOMITING		
CORN STARCH	YES	HIST
CORRECTOL	YES	HIST
CORTICOTROPIN	YES	HIST
CORTICOTROPIN/ZINC HYDROXIDE	YES	HIST
EYE WASHES/LUBRICANTS	NO	OBS
Reactions: DROWSINESS		
FILGRASTIM	YES	HIST
HAYFEBROL SF	NO	HIST
Reactions: ITCHING, WATERING EYES		
LOMEFLOXACIN	YES	OBS
Reactions: ITCHING, WATERING EYES (Mar 10, 1999)		
OXYCODONE	YES	HIST
PENICILLINS	NO	HIST

PENTAMIDINE	YES	HIST
PENTAZOCINE	YES	HIST
PENTETIC ACID	YES	HIST
RANITIDINE	YES	OBS
Reactions: CHILLS (Nov 26, 2002@11:16)		
TACRINE	YES	HIST
TAPE	YES	HIST
TAVIST	NO	HIST
TAVIST	NO	HIST
WARFARIN	YES	HIST
WATER	NO	HIST
ZANTAC	YES	HIST
TYPE: DRUG, FOOD		
=======================================		
CHOCOLATE	YES	HIST
FLUPHENAZINE DECANOATE	NO	HIST
PEANUT OIL	NO	OBS
Reactions:		
ITCHING, WATERING EYES (Oct 05, 2000@24:00),		
ANXIETY (Oct 06, 2000@09:27) SHELL FISH	NO	III CM
SUEDT LISU	NO	HIST
TYPE: FOOD		
========		
NUTS	YES	HIST
Reactions: HIVES (Jan 02, 1998)	1110	11101
PEACHES	YES	HIST
STRAWBERRIES	YES	HIST
TYPE: OTHER		
========		
DUST	YES	HIST
Enter RETURN to continue or '^' to exit:		

# **Edit Chart and ID Band**

This option allows you to indicate if the patient ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking User Menu Option: 3 Edit Chart and ID Band
Select Patient: ARTPATIENT, TWO
                                     10-04-69 666110222 SC VETERAN
CHOOSE FROM:
   ASPIRIN
   COD LIVER OIL
   DEMECARIUM
   FROGS
   PENBUTOLOL
   PENICILLIN
   PHENOBARBITAL
   PHENYTOIN
   PREDNISONE
   THOR - PROM
   TIMOLOL
   TYLOXAPOL
Select CAUSATIVE AGENT: ASPIRIN 10-04-69 666110222 SC VETERAN
ASPIRIN
Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 666110222
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
PENICILLIN
ASPIRIN
Have the Chart(s) been marked for these CAUSATIVE AGENTS? ??
ANSWER YES IF THE Chart(s) HAS BEEN MARKED, ELSE ANSWER NO.
Have the Chart(s) been marked for these CAUSATIVE AGENTS? Y (Yes)
```

# List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Adverse Reaction Tracking User Menu Option: 4 List by Location of Unmarked ID Bands/Charts

1 Current Inpatients
2 Outpatients over Date/Time range
3 New Admissions over Date/Time range
4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):
4
Enter date/time range in which patients were admitted into the hospital or seen at an outpatient clinic.
Enter START Date (time optional): T-90 (MAR 30, 2004)
Enter END Date (time optional): T// < Enter> (JUN 28, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?
   You may deselect from the list by typing a '-' followed by location
   E.g. -3E would delete 3E from the list of locations already
   selected.
   You may enter the word ALL to select all appropriate locations.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
   1N
   15
   GMC DR. PETIT
  PHYSICAL EXAM
Select Location: 1N
Another Location: < Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// <Enter> (JUN 28 2004@13:42:26)
Request queued...
Ju 28, 2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
```

Jun 28,2004	CURRENT INPATIENTS / OUTPA	RKED ID BAND/CHART ATIENTS / NEW ADMISSIONS TO Jun 28,2004@24:00	PAGE 1
PATIENT	SSN	ALLERGY	UNMARKED
WARD	: 1A(1&2)		
ARTPATIENT, ONE	666-11-0111	AMPICILLIN ASPIRIN CHOCOLATE MILK OF MAGNESIA AMOXICILLIN PENICILLIN	ID BAND/CHART
ARTPATIENT, TWO	666-11-0222	2 AMOXICILLIN DUST ZANTAC	ID BAND/CHART ID BAND/CHART ID BAND/CHART ID BAND/CHART
ARTPATIENT, THREE Enter RETURN to	EE 666-11-0333 o continue or '^' to exit:	CEPHALEXIN TABLETS,	
Jun 28,2004	CURRENT INPATIENTS / OUTPA	RKED ID BAND/CHART ATIENTS / NEW ADMISSIONS TO Jun 28,2004@24:00	PAGE 2
PATIENT	SSN	ALLERGY	UNMARKED
un 28,2004	CURRENT INPATIENTS / OUTPA	CHEESE  BARIUM SULFATE  OPIOID ANALGESICS  RADIOLOGICAL/CONTRAS  FOLIC ACID  STRAWBERRIES  PENICILLIN  KED ID BAND/CHART  ATIENTS / NEW ADMISSIONS  TO Jun 28,2004@24:00	ID BAND/CHART ID BAND/CHART ID BAND/CHART ID BAND/CHART ID BAND/CHART
PATIENT	SSN	ALLERGY	UNMARKED
ARTPATIENT, FOUR ARTPATIENT, FIVE		STRAWBERRIES	ID BAND/CHART ID BAND/CHART ID BAND/CHART

# **Patient Allergies Not Signed Off**

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO//
DEVICE: HOME// < Enter> HYPER SPACE
                 ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                      Run Date/Time: 6/28/04 9:18:26 am
                                                            ORIGINATION
ORIGINATOR
                        PATIENT
                                            ALLERGY
DATE/TIME
______
PROVIDER, ONE ARTPATIENT, ONE (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER, ONE ARTPATIENT, ONE (0111) FROG FEB 18, 2003@15:14
PROVIDER, ONE ARTPATIENT, ONE (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER, ONE ARTPATIENT, TWO (0112) PENICILLIN JUN 22, 2003@11:44 PROVIDER, ONE ARTPATIENT, TWO (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER, ONE ARTPATIENT, TWO (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER, ONE ARTPATIENT, TWO (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER, ONE ARTPATIENT, TWO (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER, ONE ARTPATIENT, TWO (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER, ONE ARTPATIENT, TWO (0112) CODEINE JUN 30, 2003@08:55
PROVIDER, ONE ARTPATIENT, TWO (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER, ONE ARTPATIENT, TWO (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER, ONE ARTPATIENT, THREE (0113) CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER, ONE ARTPATIENT, THREE (0113) SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER, ONE ARTPATIENT, THREE (0114) DUCK JAN 06, 2004@11:13
Enter RETURN to continue or '^' to exit: ^
```

# **List by Location of Undocumented Allergies**

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of Undocumented Allergies

1 Current Inpatients
2 Outpatients over Date/Time range
3 New Admissions over Date/Time range
4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??
    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
  Choose from:
   1 CARY'S CLINIC
   13A PSYCH
  1A(1&2)
   2B MED
   8E REHAB MED
   8W SUBSTANCE ABUSE
   CARDIOLOGY
   CT ROOM
Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...
```

Jul 2,2004 CURRENT	INPATIENTS / OUTPAT	ABOUT ALLERGIES TIENTS / NEW ADMISSIONS TO Jul 2,2004@24:00	PAGE 1
PATIENT	SSN	PROVIDER	
WARD: 1A(1&2	)		
ARTPATIENT, ONE		ARTPROVIDER, ONE	
ARTPATIENT, TWO	666-00-1112P		
ARTPATIENT, TWO	666-00-1112		
		ARTPROVIDER, TWO	
Room/Bed: B-2			
ARTPATIENT, THREE	666-12-4443	ARTPROVIDER, THREE	
Room/Bed: 9-B ARTPATIENT,FOUR	666-00-1114		
ARIPATIENT, FOUR ARTPATIENT, FIVE	666-00-1114		
Enter RETURN to contin			
	01 00 01110		
Jul 2,2004	PATIENTS NOT ASKED	ABOUT ALLERGIES	PAGE 2
CURRENT		CIENTS / NEW ADMISSIONS	
	FROM Jan 4,2004	TO Jul 2,2004@24:00	
PATIENT	SSN	PROVIDER	
WARD: 2B MED			
ARTPATIENT, SIX ARTPATIENT, SEVEN	666-00-1116	ARTPROVIDER, FOUR	
ARTPATIENT, SEVEN	666-00-111/		
Enter RETURN to contin	ue or '^' to exit:		
Jul 2,2004	PATIENTS NOT ASKED	ABOUT ALLERGIES	PAGE 3
*		CIENTS / NEW ADMISSIONS	
	FROM Jan 4,2004	TO Jul 2,2004@24:00	
PATIENT	SSN		
CLINIC: CARD	TOLOGY		
		ARTPROVIDER, FIVE	
ARTPATIENT, NINE	666-00-1119		
ARTPATIENT, EIGHT ARTPATIENT, NINE ARTPATIENT, TEN	666-00-1119 666-00-1110		
Enter RETURN to contin	ue or '^' to exit:		

If you select a ward/clinic location where no patients meet the report's criteria (i.e., all patients were asked about allergies), then an appropriate message will appear (No Patients for this Ward).

# **Print Patient Reaction Data**

This option will allow you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Select PATIENT: ARTPATIENT, ONE 10-12-69 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1
DEVICE: HOME// < Enter> HYPER SPACE
               ALLERGY/ADVERSE REACTION REPORTS
                Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT, ONE
                666-00-0111 FEB 22,1942 (62)
STATUS: ACTIVE
 TYPE: DRUG
 _____
      AGENT: ALLENT
 INGREDIENTS: PSEUDOEPHEDRINE
                             VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
            BROMPHENIRAMINE
   ORIGINATOR: CRPROVIDER, ONE
                                      ORIGINATED: MAR 17, 2004@14:34
    SIGN OFF: YES
                                       OBS/HIST: HISTORICAL
ID BAND MARKED:
                                     CHART MARKED: MAR 17, 2004@14:34:16
    MECHANISM: ALLERGY
ARTPATIENT,ONE 666-00-0111 FEB 22,1942 (62)
    VERIFIER: AUTOVERIFIED
                                        VERIFIED: MAR 17, 2004@14:34:17
```

AGENT: ALUMINUM ACETATE

INGREDIENTS: ALUMINUM ACETATE VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER,ONE ORIGINATED: NOV 26, 2002@11:25

SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: CHILLS (Nov 25, 2002)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED VERIFIED: NOV 26, 2002@11:26:27

AGENT: AMOXICILLIN

INGREDIENTS: AMOXICILLIN VA DRUG CLASSES: PENICILLINS, AMINO DER

ORIGINATOR: ARTPROVIDER, TWO ORIGINATED: JAN 21, 1998@10:20

SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

AGENT: AMPICILLIN

INGREDIENTS: AMPICILLIN VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER,ONE ORIGINATED: JAN 21, 1998@10:25

SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

# Adverse Reaction Tracking Clinician Menu

This menu is assigned to all clinicians of Adverse Reaction Tracking who are not verifiers or ADP coordinators. The options on this menu allow users to enter, edit, and display allergy data, enter Food and Drug Administration report data, run various reports of importance to the clinician, and edit the patient's chart and identification band.

This menu should only be given to the clinicians of ART. This option contains the following options:

- 1. Enter/Edit Patient Reaction Data
- 2. FDA Enter/Edit Menu ...
- 3. Reports Menu ...
- 4. Edit Chart and ID Band
- 5. Online Reference Card

# **Enter/Edit Patient Reaction Data**

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 40 for descriptions of the prompts for this option. Enter/Edit Patient Reaction Data

### **Example**

```
Select Adverse Reaction Tracking Clinician Menu Option: 1 Enter/Edit Patient Re
action Data
Select PATIENT NAME: CPRSPATIENT, TWO
                                          2-22-42 666324321
                                                                  YES
ACTIVE DUTY
Enrollment Priority: Category: NOT ENROLLED End Date: 07/06/2004
                                                                  OBS/
REACTANT
                                                   VER. MECH.
                                                                 HIST
                                                                       TYPE
                                                   ____
                                                                 ____
ACE INHIBITORS
                                                   NO UNKNOWN HIST DRUG
                                                   AUTO ALLERGY HIST DRUG
ALLENT
(BROMPHENIRAMINE, PSEUDOEPHEDRINE)
                                                   AUTO UNKNOWN HIST DRUG
ALUMINUM ACETATE
   Reactions: CHILLS
                                                         UNKNOWN HIST
AMOXICILLIN
                                                   YES
                                                                       DRUG
AMPICILLIN
                                                   YES
                                                         UNKNOWN HIST
                                                                       DRUG
BILBERRY
                                                   AUTO UNKNOWN HIST
                                                                       DRUG
(BILBERRY EXTRACT)
CANDESARTAN
                                                   AUTO ALLERGY HIST
                                                                       DRUG
                                                        ALLERGY HIST
                                                                       DRUG
CARAMEL
                                                   YES
   Reactions: HIVES, ITCHING, WATERING EYES
                                                   AUTO ALLERGY OBS
                                                                       DRUG
CORICIDIN TAB
   Reactions: CHILLS, HYPOTENSION, NAUSEA, VOMITING
CORN STARCH
                                                   AUTO ALLERGY HIST DRUG
(CORN OIL)
CORRECTOL
                                                   AUTO ALLERGY HIST DRUG
                                                   AUTO PHARM HIST DRUG
CORTICOTROPIN
Press RETURN to continue or '^' to stop listing: ^
Enter Causative Agent: cheese
Checking existing PATIENT ALLERGIES (#120.8) file for matches...
Now checking GMR ALLERGIES (#120.82) file for matches...
  CHEESE OK? Yes// <Enter> (Yes)
(O)bserved or (H)istorical Allergy/Adverse Reaction: o OBSERVED
Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004) DEC 06,
2004 (DEC 06, 2004)
 Are you adding 'DEC 06, 2004' as
   a new ADVERSE REACTION REPORTING? No// y (Yes)
```

```
No signs/symptoms have been specified. Please add some now.
The following are the top ten most common signs/symptoms:
1. CHILLS
                               7. HIVES
2. ITCHING, WATERING EYES
                              8. DRY MOUTH
3. HYPOTENSION
                               9. DRY NOSE
4. DROWSINESS
                               10. RASH
5. NAUSEA, VOMITING
                               11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter> (DEC 06,
2004)
The following is the list of reported signs/symptoms for this reaction:
   Signs/Symptoms
                                              Date Observed
______
1 RASH
                                              Dec 06, 2004
Select Action (A)DD, (D)ELETE OR <RET>: <RET>
COMMENTS:
Complete the observed reaction report? Yes// <RET> (Yes)
DATE/TIME OF EVENT: DEC 6,2004//
OBSERVER: CPRSPROVIDER, EIGHT BCC Chief Medical Officer
SEVERITY: m
   1 MILD
   2 MODERATE
Choose 1-2: 1 MILD
DATE MD NOTIFIED: Dec 6,2004// <Enter> (DEC 06, 2004)
Enter another Causative Agent? YES// n NO
                          Dec 06, 2004@14:02:53
Causative Agent Data edited this Session:
ADVERSE REACTION
______
 CHEESE
         Obs/Hist: OBSERVED
          Obs d/t: Dec 06, 2004
    Signs/Symptoms: RASH (12/6/04)
Is this correct? NO// y YES
Enter Hospital Location:
Opening Adverse React/Allergy record for review...
                             Dec 06, 2004@14:02:53 Page: 1 of 1
Browse Document
                           Dec 00, 200101
Adverse React/Allergy
Visit Date: 12/06/2004 14:02
CPRSPATIENT, T 666-32-4321
DATE OF NOTE: DEC 06, 2004@14:02:50 ENTRY DATE: DEC 06, 2004@14:02:52
     AUTHOR: CRPROVIDER, TWO
                                    EXP COSIGNER:
    URGENCY:
                                        STATUS: UNSIGNED
This patient has had the following reactions
```

signed-off on Dec 06, 2004@14:02:50.

CHEESE

+ Next Screen - Prev Screen ?? More actions

Link ...

Quit

Find Print Sign/Cosign

Copy Identify Signers Encounter Edit Edit Interdiscipl'ry Note

Make Addendum Delete

Select Action: Quit//<Enter>
Select PATIENT NAME: <Enter>

# FDA Enter/Edit Menu (Clinician)

This menu should be given to users responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu allow users to enter and edit the FDA data.

- 1. Enter/Edit FDA Report Data
- 2. Enter/Edit P&T Committee Data

# **Enter/Edit FDA Report Data**

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15-day report was completed and the type of the report (e.g., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data
Select PATIENT NAME: ARTpatient, Two 04-25-31 666001112 SC VETERAN
Select CAUSATIVE AGENT: ASPIRIN 10-04-69 666001112 SC VETERAN
        ASPIRIN
Select date reaction was OBSERVED (Time Optional): T-10 (JAN 13, 2004) JAN
 13, 1996 (JAN 13, 2004)
 Are you adding 'JAN 13, 2004as
 a new ADVERSE REACTION REPORTING? Y (Yes)
Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): 1
The following is the list of reported signs/symptoms for this reaction:
   Signs/Symptoms
 1 ANXIETY
Select Action (A)DD OR (D)ELETE: A
```

```
The following are the top ten most common signs/symptoms:
1. ANXIETY 7. HIVES
2. ITCHING, WATERING EYES 8. DRY MOUTH
3. HYPOTENSION 9. CHILLS
4. DROWSINESS 10. RASH
5. CHEST PAIN 11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 7
The following is the list of reported signs/symptoms for this reaction:
  Signs/Symptoms
 1 ANXIETY
 2 HIVES
Select Action (A)DD OR (D)ELETE: < Enter>
Patient died?: N NO
Reaction treated with RX drug?: N NO
Life Threatening illness?: N NO
Required hospitalization?: N NO
Prolonged Hospitalization?: N NO
Resulted in permanent disability?: N NO
Is this event a Congenital Anomaly?: N NO
Did this event require intervention to prevent impairment/damage?: N NO
THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD
View Tx/Test from: JAN 13, 2004// < Enter> (JAN 13, 2004)
To: JAN 13, 2004// < Enter> (JAN 13, 2004)
LAB TEST:
   Collection DT Test Name Specimen Results Hi/Low
   THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??
Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS, TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
```

Select TEST: 1/2Hr.GTT (URINE)

Are you adding '1/2Hr.GTT (URINE)' as

a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION

REPORTING)? Y (Yes)

RESULTS: ??

This field will contain the results for the particular test.

RESULTS: Enter results here.

COLLECTION D/T: **T-10** (JAN 13, 2004)

Select TEST:

This patient has the following Test selected:

TEST/TX RESULTS DRAW DATE/TIME

1) 1/2Hr.GTT (URINE) Enter results here. 01/13/96

Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: < Enter>

- 1. Reaction Information
- 2. Suspect Drug(s) Information
- 3. Concomitant Drugs and History
- 4. Manufacturer Information
- 5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): < Enter>

# **Enter/Edit P&T Committee Data**

This option will allow you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data
Select PATIENT NAME: ARTpatient, One 10-04-69 666110111 SC VETERAN
Select CAUSATIVE AGENT: PENICILLIN 10-04-69 666110111 SC VETERAN PENICILLIN
Select date reaction was OBSERVED (Time Optional): T (JAN 24, 2004) JAN
24, 2004 (JAN 24, 2004)
 Are you adding 'JAN 24, 2004as
  a new ADVERSE REACTION REPORTING? Y (Yes)
P&T Report Completion
Serious ADR?: ??
   This field determines if the reaction is considered serious.
   Choose from:
    y YES
    n NO
Serious ADR?: y YES
ADR related to new drug?: n NO
Unexpected ADR?: y YES
ADR related to therapeutic failure?: n NO
Dose related?: n NO
P&T ACTION FDA REPORT: ??
     This field indicates if the P&T committee determined whether to send
     the report to FDA.
     Choose from:
      y YES
       n NO
P&T ACTION FDA REPORT: n NO
P&T ACTION MFR REPORT: n NO
ADDENDUM:
 1>ADD COMMENTS HERE
EDIT Option: < Enter>
Select PATIENT NAME: < Enter>
```

# Reports Menu (Clinician)

This menu is part of the Adverse Reaction Tracking Clinician Menu. It is the only print option that the clinician needs for ART.

- 1. Active Listing of Patient Reactions
- 2. Print Patient Reaction Data
- 3. Print an FDA report for a Patient
- 4. List by Location of Unmarked ID Bands/Charts
- 5. Patient Allergies Not Signed Off
- 6. List by Location of Undocumented Allergies
- 7. List by Location Not Verified Reactions
- 8. List by Location and Date all Sign Reaction
- 9. List FDA data by Report Date

# Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to a printer for a hard copy printout or displayed to the terminal screen. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified. If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select Reports Menu Option: 1 Active Listing of Patient Reactions				
Select PATIENT: ARTpatient, One 10-04-69 666000111 ACTIVE DUTY				
DEVICE: HOME// < Enter> HYPER SPACE				
ACTIVE ALLERGY/ADVERSE REACTION LISTING Run Date/Time: 7/6/04 1:51:13 pm				
ARTPATIENT, ONE 666122222 APR 25, 193	31 (73)			
		OBS/		
ADVERSE REACTION V	ERIFIED	HIST		
TYPE: DRUG				
======= ACETAMINOPHEN	NO	OBS		
Reactions: ANXIETY (Jun 06, 2001@10:21)				
ACETANILIDE Reactions: CHILLS	NO	HIST		
ALOE VERA	YES	OBS		
Reactions: ANXIETY (Mar 06, 1997)	NO	HT OFF		
ASPIRIN Reactions: RASH (Oct 31, 2001)	NO	HIST		
ASPIRIN/BUTALBITAL/CAFFEINE	NO	HIST		
Reactions: NAUSEA, VOMITING (Oct 31, 2001) BARIUM SULFATE	YES	OBS		
Reactions: HIVES	110	OBB		
BERROPLEX Reactions: DROWSINESS	NO	HIST		
CEPHALEXIN TABLETS, 250MG	YES	OBS		
Reactions: THROMBOCYTOPENIA				
DILANTIN Reactions: CHILLS	NO	OBS		
ERYTHROMYCINS/MACROLIDES	YES	OBS		
Reactions: ITCHING, WATERING EYES (Mar 06, 1997) GREEN SOAP	YES	OBS		
Reactions: ANXIETY (May 19, 1997@14:25)	IES	OBS		
GREEN SOAP TINCTURE	YES	OBS		
Reactions: DRY MOUTH (May 19, 1997@14:23) HALENOL 500MG CAPSULES	YES	HIST		
Reactions: ANXIETY (May 19, 1997@14:26)				
HAYFEBROL SF Reactions: CHILLS, ITCHING, WATERING EYES	NO	HIST		
OPIOID ANALGESICS	NO	OBS		
Reactions: ITCHING, WATERING EYES	NO	ODG		
PENICILLIN	NO	OBS		

Reactions: NAUSEA, VOMITING, DIARRHEA PENICILLINS, AMINO DERIVATIVES Reactions: DEPRESSION (Jan 01, 1980) RADIOLOGICAL/CONTRAST MEDIA Reactions: HIVES	YES YES	HIST OBS
WARFARIN	YES	OBS
Reactions: HIVES (Mar 01, 1996)		
TYPE: DRUG, FOOD		
ANDIDADIEC CEDIM	NO	ODG
ANTIRABIES SERUM Reactions: CHILLS (Jun 08, 2004)	NO	OBS
BEER	NO	HIST
Reactions: HYPOTENSION	NO	III CIII
SUNFLOWER OIL	NO	HIST
TYPE: FOOD		
======== CHEESE	YES	HIST
Reactions: NAUSEA, VOMITING, DIARRHEA	IES	птот
FOLIC ACID	YES	HIST
Reactions: DRY NOSE		0.00
STRAWBERRIES Reactions: RASH	YES	OBS
WATER	NO	HIST
Reactions: CHILLS		
Enter RETURN to continue or '^' to exit: ^		

#### Print Patient Reaction Data

This option will allow you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select PATIENT: ARTPATIENT, TWO
                                    4-25-31
                                                              YES
                                                                    MILITARY RETIREE
                                               666001112P
Enrollment Priority: GROUP 2
                                 Category: IN PROCESS
                                                      End Date:
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1
DEVICE: HOME// ;;999 ANYWHERE
                    ALLERGY/ADVERSE REACTION REPORTS
                   Run Date/Time: 7/6/04 1:54:59 pm
ARTPATIENT, TWO
                     666001112P APR 25,1931 (73)
STATUS: ACTIVE
 TYPE: DRUG
  ========
        AGENT: ACETAMINOPHEN
  INGREDIENTS: ALCOHOL
                                         VA DRUG CLASSES: NON-OPIOID ANALGESICS
                ACETAMINOPHEN
                                                          PHARMACEUTICAL AIDS/R
               PHENYLALANINE
                                             ORIGINATED: JUN 06, 2001@10:21
   ORIGINATOR: ARTPROVIDER, ONE
     SIGN OFF: YES
                                                OBS/HIST: OBSERVED
ID BAND MARKED:
                                            CHART MARKED:
SIGNS/SYMPTOMS: ANXIETY (Jun 06, 2001@10:21)
     MECHANISM: UNKNOWN
        AGENT: ACETANILIDE
                                      VA DRUG CLASSES: PHARMACEUTICAL AIDS/R
   INGREDIENTS: ACETANILIDE
   ORIGINATOR: ARTPROVIDER, ONE
                                                  ORIGINATED: AUG 26, 2003@14:44
     SIGN OFF: YES
                                                OBS/HIST: HISTORICAL
ID BAND MARKED:
                                            CHART MARKED:
SIGNS/SYMPTOMS: CHILLS
```

MECHANISM: UNKNOWN

AGENT: ALOE VERA 

INGREDIENTS: ALOE VERA VA DRUG CLASSES: DERMATOLOGICALS, TOPIC

ORIGINATOR: ARTPROVIDER, THREE SIGN OFF: YES ORIGINATED: MAR 06, 1997@14:14

OBS/HIST: OBSERVED

ORIGINATOR

COMMENTS:

Date: Mar 06, 1997@14:14 User: ARTNURSE, ONE

Title: NURSE

TESTING

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: ANXIETY (Mar 06, 1997)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED VERIFIED: FEB 16, 2004@11:44:19

VERIFIER COMMENTS:

User: ARTPROVIDER,ONE Title: PHYSICIAN Date: Feb 16, 2004@11:44:19

Auto-verified by patch 19 post-install

.Enter RETURN to continue or '^' to exit: ^

# Print an FDA Report for a Patient

This option will allow you to print an individual FDA report for a patient.

This option will also produce a listing of all allergy/adverse reactions that are awaiting sign-off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```
Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT, THREE 12-01-34 666124443 SC VETERAN
Select CAUSATIVE AGENT: ??
CHOOSE FROM:
   AMPICILLIN
   CYCLOSPORINE
   GENTAMICIN
   PENICILLIN
Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
   AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
     ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.
QUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)
Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
```

MEDWatch		Approved by FDA on 10/20/93				
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM			Triage unit sequence #			
THE PDA MEDICAL PRODUCTS REPORTING PROGRAM			11	rage unit set	duence #	
	Page	1 of 1				
A. Patient Information			M-3::			
A. Patient information			C. Suspect Medication(s)			
1. Patient Indentifier 2. DOB: 12 T4443 AGE: 61 yrs FEMALE 0.0	/1/34  3. Sex 4. Weight		1. Name #1 : AMPICILLIN			
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	xxxxxxxxxxxxxxxxxxx	XXXXXXXX	XXXXXXXXXXXXXXXXXX	xxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
B. Adverse Event or Product Probl	em					
1. [X]Adverse Event [ ]Product pr	oblem	2. Dose	. Dose, frequency & route used   3. Therapy dates		3. Therapy dates	
		#1:			#1 :	
2. Outcomes attributed to adverse						
[ ] life-threatening [ ] congenit	al anomaly					
[] Hospitalization [] required		4.Diagnosis for use(indication)   5. Event abated after use				
initial or prolonged prevent impa [X] other	irment/damage	#1:			stopped or dose reduced? #1: [N/A]	
	4. Date of this report 01/30/96					
01/10/96	01/30/96	6. Lot	# (if known)	7. Exp. date	8. Event reappeared after	
5. Describe event or problem				_	reintroduction	
RASH		#1:		#1:	#1: [ ]	
		9. (Not applicable to adverse drug event reports)				
6. Relevant test/laboratory data. including dates treatment)		10. Concomitant medical products/therapy dates(exclude				
Creatment)						
7 Obban malanant Wintama inglad			D. Suspect Me	dical Devices	3	
7. Other relevant History, includ conditions	ing preexisting medical		Note: Please use the actual MedWatch form if the event			
			involves a suspected device as well as a suspect drug			
			E. Reporter			

	1. Name, address & phone #:		
Mail to: MedWatch or FAX to: 5600 Fishers Lane 1-800-FDA-0178 Rockville, MD XXXXX	2. Health professional?  3. Occupation  4. Reported to Mfr. [NO]		
Marie Control	5. If you don't want your identity disclosed to the		
Manufacturer,	place an "X" in the box. [ ]		
FDA Form 3500	=		
Submission of a report does not constitute an admission that med	ical personnel or the product caused or contributed to the event.		

### List by Location of Unmarked ID Bands/Charts

This option will find all patients in the system who have not had their ID bands or charts marked. This option will also produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

```
Select Reports Menu Option: 4 List by Location of Unmarked ID Bands/Charts

1 Current Inpatients
2 Outpatients over Date/Time range
3 New Admissions over Date/Time range
4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-90 (APR 07, 2004)
Enter END Date (time optional): T// < Enter> (JUL 06, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?
     You may deselect from the list by typing the - followed by location
     name.
     E.g. -3E would delete 3E from the list of locations already
     selected.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
    1 A
    1S
    GMC DR. PETIT
    PHYSICAL EXAM
Select Location: 1A
Another Location: < Enter>
OUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JUL 6 2004@13:42:26)
Request queued...
                 PATIENTS WITH UNMARKED ID BAND/CHART
Jul 6,2004
                                                                              PAGE 1
                CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                       FROM Apr 7,2004 TO Jul 6,2004@24:00
                                 SSN
PATTENT
                                                ALLERGY
                                                                        UNMARKED
         WARD: 1A(1&2)
                                                 Da DRUG ID BAND/CHART
DUST ID BAND/CHART
AMPICILLIN ID BAND/CHART
ASPIRIN ID BAND/CHART
CHOCOLATE ID BAND/CHART
MILK OF MAGNESIA ID BAND/CHART
AMOXICILLIN ID BAND/CHART
PENICILLIN ID BAND/CHART
MENTHOL ID BAND/CHART
ARTPATIENT, ONE
                             666-00-0111
                                                                     ID BAND/CHART
                                 666-00-1112 AMOXICILLIN
ARTPATIENT, TWO
```

		DUST	ID	BAND/CHART
		ZANTAC		BAND/CHART
ARTPATIENT, THREE	666-00-1113	CEPHALEXIN TABLETS,	ID	BAND/CHART
·		CHEESE	ID	BAND/CHART
		BARIUM SULFATE	ID	BAND/CHART
		OPIOID ANALGESICS	ID	BAND/CHART
		RADIOLOGICAL/CONTRAS	ID	BAND/CHART
		FOLIC ACID	ID	BAND/CHART
		STRAWBERRIES	ID	BAND/CHART
ARTPATIENT, FOUR	666-00-1114	STRAWBERRIES	ID	BAND/CHART
ARTPATIENT, FIVE	666-00-1115	CHOCOLATE	ID	BAND/CHART
		BLUE CROSS AMPICILLI	ID	BAND/CHART
		ACETAMINOPHEN TAB	ID	BAND/CHART
		STRAWBERRIES		BAND/CHART
		ASPIRIN/BUTALBITAL	ID	BAND/CHART

### Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Reports Menu Option: 5 Patient Allergies Not Signed Off
DEVICE: HOME// < Enter> HYPER SPACE
ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 1/18/96 1:23:52 pm
                   PATIENT
ORIGINATOR
                                                                       ALLERGY ORIGINATION DATE/TIME
                                                                      ______
 _____
ARTPROVIDER,ONE ARTPATIENT,ONE (0111) PENICILLIN FEB 18, 1993@10:59
ARTPROVIDER,ONE ARTPATIENT,ONE (0111) FROG FEB 18, 1993@15:14
                                                                                                   FEB 18, 1993@15:14
ARTPROVIDER, ONE ARTPATIENT, TWO (0112) THORAZINE 10MG FEB 22, 1993@13:20
ARTPROVIDER, ONE ARTPATIENT, TWO (0112) THORAZINE 10MG FEB 22, 1993@13:20

ARTPROVIDER, ONE ARTPATIENT, THREE (0113) PENICILLIN JUN 22, 1993@11:44

ARTPROVIDER, ONE ARTPATIENT, THREE (0113) PHENYTOIN JUN 22, 1993@11:48

ARTPROVIDER, ONE ARTPATIENT, THREE (0113) DEMECARIUM JUN 22, 1993@12:00

ARTPROVIDER, ONE ARTPATIENT, THREE (0113) ASPIRIN JUN 22, 1993@12:08

ARTPROVIDER, ONE ARTPATIENT, FOUR (0114) PHENOBARBITAL JUN 25, 1993@10:33

ARTPROVIDER, ONE ARTPATIENT, THREE (0113) PHENOBARBITAL JUN 25, 1993@10:39

ARTPROVIDER, ONE ARTPATIENT, TWO (0112) CODEINE JUN 30, 1993@08:55

ARTPROVIDER, ONE ARTPATIENT, FIVE (0115) THOR - PROM AUG 11, 1993@10:35
ARTPROVIDER, ONE ARTPATIENT, FIVE (0115) IMMUNE GLOBULIN AUG 18, 1993@10:02
ARTPROVIDER, ONE ARTPATIENT, FIVE (0115) CYCLOBENZAPRINE JUL 11, 1994@14:11
                            ARTPATIENT, FIVE (0115)
                                                                       SULFABENZAMIDE/S JUL 11, 1994@14:14
ARTPROVIDER, ONE
Enter RETURN to continue or '^' to exit: ^
```

### List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of Undocumented
Allergies
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
 Enter date/time range in which patients were
 admitted into the hospital or seen at an outpatient clinic.
Enter START Date (time optional): T-180 (JAN 08, 2004)
Enter END Date (time optional): T// (JUL 06, 2004)
Select Location: 2B MED
Another Location: 1A(1&2)
Another Location: < Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JAN 19, 1996@10:29:44)
Request queued...
Jul 6,2004
                      PATIENTS NOT ASKED ABOUT ALLERGIES
                                                                    PAGE 1
               CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                      FROM Jan 8,2004 TO Jul 6,2004@24:00
PATIENT
                                            PROVIDER
                             SSN
         WARD: 1A(1&2)
ARTPATIENT, FIVE
                          666-00-0115
                                         ARTPROVIDER, ONE
ARTPATIENT, THREE
                        666-00-0113
                           666-00-0112 ARTPROVIDER, TWO
ARTPATIENT, TWO
    Room/Bed: B-2
                           666-00-0114 ARTPROVIDER, FOUR
ARTPATIENT, FOUR
    Room/Bed: 9-B
Enter RETURN to continue or '^' to exit:<Enter>
Jul 6.2004
                      PATIENTS NOT ASKED ABOUT ALLERGIES
                                                                     PAGE 2
              CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                FROM Jan 8,2004 TO Jul 6,2004@24:00
                                           PROVIDER
PATIENT
                             SSN
         WARD: 2B MED
ARTPATIENT, SIX 666-00-0116 ARTPROVIDER, FOUR ARTPATIENT, SEVEN 666-00-0117 ARTPROVIDER, FOUR
Enter RETURN to continue or '^' to exit: <Enter>
```

#### List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.

The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 7 List by Location Not Verified Reactions
DEVICE: HOME//
                   ANYWHERE
Report Date: Jul 06, 2004
                                                                      Page: 1
                     List of Unverified Reactions by Ward Location
                                 Ward Location: 13A PSYCH
   Origination Date/Time
                                 Originator
                                                             Reaction
ARTPATIENT, ONE (666-00-0111)
   Jul 16, 2003@11:49
                                 ARTPROVIDER, ONE
                                                            RANITIDINE
ARTPATIENT, TWO (666-00-0112)
Jul 09, 1996@08:04
ARTPATIENT,THREE (666-00-0113)
                                 ARTPROVIDER, TWO
                                                            STRAWBERRIES
   Jul 09, 1996@08:04
                                 ARTPROVIDER, TWO
                                                            DUST
ARTPATIENT, FOUR (666-00-0114)
                                                            FISH LIVER OIL
   Jul 09, 1996@08:04
                                 ARTPROVIDER, TWO
ARTPATIENT, FIVE (666-00-0115)
  May 24, 1999@14:21
Jul 02, 1999@13:40
Aug 20, 1999@09:27
                                 ARTPROVIDER, THREE
                                                            MILK
                                 ARTPROVIDER, THREE
                                                            BERGAMOT
                                 ARTPROVIDER, THREE
                                                            RANITIDINE
Enter RETURN to continue or '^' to exit:
```

#### List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.

The header of the report contains the title, the date range selected by you, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option: List by Location and Date All Signed
Reactions
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)
DEVICE: HOME//
                  ANYWHERE
One moment please...
Jul 06, 2004
                                                                    Page: 1
            List all Signed Patient Reactions for Ward Location 1A(1&2)
              From Jan 08, 2004 to Jul 06, 2004@24:00
Date
                   Originator
                                                Type Causative Agent
Patient: ARTPATIENT,SIX (666-00-0116)
Jan 12, 2004@12:56 ARTPROVIDER,ONE
Jun 11, 2004@15:25 ARTPROVIDER,TWO
                                                   D HAYFEBROL SF
                                                   D DIRITHROMYCIN
Jun 08, 2004@12:15 ARTPROVIDER, THREE
                                                   DF ANTIRABIES SERUM
           Patient: ARTPATIENT, SEVEN (666-00-0117)
Feb 26, 2004@11:29 ARTPROVIDER,ONE
                                                D ZANTAC
                                                  D
May 04, 2004@10:52 ARTPROVIDER, ONE
                                                      FORMALDEHYDE
May 04, 2004@10:55 ARTPROVIDER, ONE
                                                  D
                                                      CONTACT LENS WETTING
SOLN
May 04, 2004@10:56 ARTPROVIDER,ONE May 04, 2004@10:57 ARTPROVIDER,ONE
                                                  D
                                                      NICO 400
                                                  DF CORN
May 04, 2004@11:00 ARTPROVIDER, ONE
                                                  DF BCG VACCINE
           Patient: ARTPATIENT, EIGHT (666-00-0118)
Feb 26, 2004@11:31 ARTPROVIDER, ONE
                                                  D
                                                       ZANTAC
           Patient: ARTPATIENT, NINE (666-00-0119)
Feb 05, 2004@10:51 ARTPROVIDER, TWO
                                                      STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

#### List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)
DEVICE: HOME//
                ANYWHERE
Report Date: Jul 06, 2004
                                                              Page: 1
                     Adverse Reaction Tracking Report
                        From: 1/8/04 To: 7/6/04
Patient
                                      Dates Related Reaction
ARTPATIENT, ONE
                              Obs DT: 1/27/04 DUST
(666-00-1111)
                              Trk DT: 1/27/04
                              ______
Loc: 1A(1&2)
                                0 Days Difference
Obs: ARTPROVIDER, ONE
                             Obs DT: 1/30/04 CHOCOLATE
Trk DT: 1/30/04
ARTPATIENT, TWO
(666-00-1112)
Loc: OUT PATIENT
Obs: ARTPROVIDER, ONE
                              0 Days Difference
                     Obs DT: 1/30/04 CHOCOLATE Trk DT: 1/30/04
ARTPATIENT, THREE
(355-67-1996)
Loc: 8E REHAB MED
Obs: ARTPROVIDER, ONE
                              0 Days Difference
                                               ZANTAC
ARTPATIENT, FOUR
                              Obs DT: 2/2/04
(666-00-0114)
                              Trk DT: 2/2/04
Loc: 1A(1&2)
Obs: ARTPROVIDER, ONE
                                0 Days Difference
Enter RETURN to continue or '^' to exit:
```

#### **Edit Chart and ID Band**

This option allows you to enter whether a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking Clinician Menu Option: 4 Edit Chart and
ID Band
Select Patient: ARTPATIENT, ONE 10-04-69 666122222 SC VETERAN
CHOOSE FROM:
   ASPIRIN
   COD LIVER OIL
   DEMECARIUM
   FROGS
   PENBUTOLOL
   PENICILLIN
   PHENOBARBITAL
   PHENYTOIN
   PREDNISONE
   THOR - PROM
   TIMOLOL
   TYLOXAPOL
Select CAUSATIVE AGENT: ASPIRIN 10-04-69 123122222 SC VETERAN
ASPIRIN
Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 123122222
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
    PENICILLIN
    ASPIRIN
Has the ID Band been marked for these CAUSATIVE AGENTS? ??
    ANSWER YES IF THE ID Band HAS BEEN MARKED, ELSE ANSWER NO
Have the Chart(s) been marked for these CAUSATIVE AGENTS? {\bf Y} (Yes)
```

# Adverse Reaction Tracking Verifier Menu

This menu should be given to the verifiers of the Adverse Reaction Tracking data. The options on this menu will allow you to edit/verify/print the data.

This menu should *only* be given to the verifiers of ART.

- 1. Enter/Edit Patient Reaction Data
- 2. Verify Patient Reaction Data
- 3. Reports Menu ...
- 4. Edit Chart and ID Band
- 5. FDA Enter/Edit Menu ...
- 6 Online Reference Card

#### **Enter/Edit Patient Reaction Data**

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs or symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 10 for descriptions of the prompts for this option.

#### Example

```
Select Adverse Reaction Tracking Verifier Menu Option: 1 Enter/Edit Patient Reaction
Data
Select PATIENT NAME: ARTPATIENT, ONE
                                        1-1-51
                                                   666111995
                                                                       EMPLOYEE
Enrollment Priority: GROUP 7 Category: IN PROCESS End Date:
                                                                 OBS/
REACTANT
                                                   VER. MECH. HIST TYPE
                                                   ____
                                                        _____
                                                                 ____
CHOCOLATE
                                                   AUTO ALLERGY HIST DRUG
(CHOCOLATE FLAVORING)
                                                                       FOOD
   Reactions: CHILLS, DROWSINESS, DRY MOUTH
Enter Causative Agent: straw
Checking existing PATIENT ALLERGIES (#120.8) file for matches...
Now checking GMR ALLERGIES (#120.82) file for matches...
BERRIES
  STRAWBERRIES OK? Yes// <Enter>
                                    (Yes)
(O)bserved or (H)istorical Allergy/Adverse Reaction: o OBSERVED
Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004) DEC 06,
2004 (DEC 06, 2004)
 Are you adding 'DEC 06, 2004' as
   a new ADVERSE REACTION REPORTING? No// y (Yes)
No signs/symptoms have been specified. Please add some now.
The following are the top ten most common signs/symptoms:
1. CHILLS
                                  7. HIVES
2. ITCHING, WATERING EYES
                                 8. DRY MOUTH
3. HYPOTENSION
                                 9. DRY NOSE
4. DROWSINESS
                                 10. RASH
5. NAUSEA, VOMITING
                                 11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above: 10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter>
                                                                          (DEC 06,
2004)
The following is the list of reported signs/symptoms for this reaction:
                                                   Date Observed
    Signs/Symptoms
```

1 RASH Dec 06, 2004 Select Action (A)DD, (D)ELETE OR <RET>: <Enter> COMMENTS: 1> Complete the observed reaction report? Yes// **<Enter>** (Yes) DATE/TIME OF EVENT: DEC 6,2004// <Enter> OBSERVER: ARTPROVIDER, TEN PHYSICIAN SEVERITY: mi MILD DATE MD NOTIFIED: Dec 6,2004// <Enter> (DEC 06, 2004) Enter another Causative Agent? YES//  $\boldsymbol{n}$  NO Dec 06, 2004@15:01:50 Causative Agent Data edited this Session: ADVERSE REACTION STRAWBERRIES Obs/Hist: OBSERVED Obs d/t: Dec 06, 2004 Signs/Symptoms: RASH (12/6/04) Is this correct? NO// y YES Opening Adverse React/Allergy record for review... Dec 06, 2004@15:01:50 Page: 1 of 1 Browse Document Adverse React/Allergy Adm: 02/18/2003 Dis: CPRSPATIENTCANC666-11-1995 2B MED DATE OF NOTE: DEC 06, 2004@15:01:49 ENTRY DATE: DEC 06, 2004@15:01:50 AUTHOR: ARTPROVIDER, TEN EXP COSIGNER: **URGENCY:** STATUS: UNSIGNED This patient has had the following reactions signed-off on Dec 06, 2004@15:01:49. STRAWBERRIES + Next Screen - Prev Screen ?? More actions >>> Find Link ... Sign/Cosign Print Сору Encounter Edit Edit Identify Signers Interdiscipl'ry Note Make Addendum Delete

```
Find Sign/Cosign Link ...

Print Copy Encounter Edit

Edit Identify Signers Interdiscipl'ry Note

Make Addendum Delete Quit

Select Action: Quit// s

Enter your Current Signature Code: xxxxxx SIGNATURE VERIFIED

Print this note? Yes// n (No)

Enter another Causative Agent? YES// n NO

This session you have CHOSEN:

STRAWBERRIES

Has the ID Band been marked for this CAUSATIVE AGENT? y (Yes)??

Select PATIENT NAME: < Enter>
```

## Verify Patient Reaction Data

This option allows designated verifiers to verify the correctness of data entered by the clinical users. The verifier may select a single patient's data to verify or a list or range (e.g., 1,3,7 or 1-10) of patients to verify. The verifier may select to view/verify drug reactions only, non-drug reactions only, or drug and non-drug reactions. The reaction data is displayed and the verifier may edit the causative agent, type, ingredients, drug class, observed/historical response, signs/symptoms, and mechanism. The verifier may enter any appropriate comments.

If the verifier answers YES to the "change status of this allergy/adverse reaction to verified" prompt, the reaction will be marked as verified. If the verifier answers NO to that prompt, the reaction is marked as entered in error.

If no hospital location is associated with the patient, the verifier will be prompted to enter a location.

A progress note is created. The verifier may electronically sign, edit, or delete the progress note. The verifier may print the progress note, too.

```
Select Adverse Reaction Tracking Verifier Menu Option: 2 Verify Patient
Reaction Data
Would you like to verify a single patient's data? NO// YES
Select PATIENT NAME: CPRSPATIENT, FIVE
                                            4-30-44
                                                       666466680
                                                                     YES
EMPLOYEE
Enrollment Priority: GROUP 2 Category: IN PROCESS
                                                       End Date:
                   D Drug
                   N Non-drug
                   В
                      Both
Select type of AGENT to verify: (D/N/B): DRUG
                                                           OBS/
 PATTENT
                                      ALLERGY
                                                           HIST ADR TYPE
  _ _ _ _ _ _ _
                                      -----
                                                           ____
1. CPRSPATIENT, FIVE (6680) 1A(1&2)
                                    ANTIRABIES SERUM
                                                           OBS UNK DRUG
                                                                    FOOD
2. CPRSPATIENT, FIVE (6680) 1A(1&2)
                                    ASPARTAME
                                                          OBS UNK DRUG
                                                                    FOOD
3. CPRSPATIENT, FIVE (6680) 1A(1&2)
                                    ASPIRIN
                                                           HIST UNK DRUG
                                                                    FOOD
Select a number between 1-3: 1
      PATIENT: CPRSPATIENT, FIVE
                                       CAUSATIVE AGENT: ANTIRABIES SERUM
  INGREDIENTS: ANTIRABIES SERUM
                                        VA DRUG CLASSES: IMMUNE SERUMS
   ORIGINATOR: ARTPROVIDER, ONE
                                       ORIGINATED: Jun 08, 2004@12:15
     SIGN OFF: YES
                                               OBS/HIST: OBSERVED
                                                OBS D/T: Jun 08, 2004@12:15
    ORIGINATOR
     COMMENTS:
         Date: Jun 08, 2004@12:16:50
                                                  User: CPRSPROVIDER, TWO
                                                  Title:
               chills and sweating
```

ID BAND MARKED: CHART MARKED: SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15) MECHANISM: UNKNOWN Is the reaction information correct? Yes// <Enter> (Yes) CAUSATIVE AGENT: ANTIRABIES SERUM TYPE: DRUG, FOOD INGREDIENTS: ANTIRABIES SERUM VA DRUG CLASSES: IM400 - IMMUNE SERUMS OBS/HIST: OBSERVED SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15) MECHANISM: UNKNOWN Would you like to edit any of this data? N (No) ORIGINATOR COMMENTS: Date: Jun 08, 2004@12:16:50 User: CPRSPROVIDER, TWO Title: chills and sweating COMMENTS: 1> PATIENT: CPRSPATIENT, FIVE CAUSATIVE AGENT: ANTIRABIES SERUM INGREDIENTS: ANTIRABIES SERUM VA DRUG CLASSES: IMMUNE SERUMS ORIGINATOR: ARTPROVIDER, TWO ORIGINATED: Jun 08, 2004@12:15 SIGN OFF: YES OBS/HIST: OBSERVED OBS D/T: Jun 08, 2004@12:15 ORIGINATOR COMMENTS: Date: Jun 08, 2004@12:16:50 User: CPRSPROVIDER, TWO Title: chills and sweating Enter RETURN to continue or '^' to exit: Dec 06, 2004@15:51:38 ID BAND MARKED: CHART MARKED: SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15) MECHANISM: UNKNOWN Change status of this allergy/adverse reaction to verified? Y (Yes) Opening Adverse React/Allergy record for review... Dec 06, 2004@15:51:38 Page: 1 of Browse Document Adverse React/Allergy CPRSPATIENT, FIVE 666-46-6680 1A(1&2) Adm: 10/15/2001 Dis: DATE OF NOTE: DEC 06, 2004@15:51:37 ENTRY DATE: DEC 06, 2004@15:51:37 AUTHOR: ARTPROVIDER, ONE EXP COSIGNER: STATUS: UNSIGNED URGENCY:

This patient has had an allergy to ANTIRABIES SERUM verified on Dec 06, 2004@15:51:37.

+ Next Screen - Prev Screen ?? More actions

Find Sign/Cosign Link ...
Print Copy Encounter Edit
Edit Identify Signers Interdiscipl'ry Note
Make Addendum Delete Quit
Select Action: Quit//

NOTE: Users can enter/edit their own electronic signature code.

## **Reports Menu (Verifier)**

This menu is part of the Adverse Reaction Tracking Verifier Menu. It is the only print menu that the verifier will need for ART.

- 1. Active Listing of Patient Reactions
- 2. Print Patient Reaction Data
- 3. Print an FDA report for a Patient
- 4. Print all FDA events within D/T range
- 5. Print Patient FDA Exception Data
- 6. Print all FDA Exceptions within a D/T range
- 7. List by Location of Unmarked ID Bands/Charts
- 8. Patient Allergies Not Signed Off
- 9. List by Location of Undocumented Allergies
- 10. List Autoverified Reaction Data
- 11. List by Location Not Verified Reactions
- 12. List by Location and Date all Sign Reactions
- 13. List FDA Data by Report Date

#### Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select PATIENT: ARTPATIENT, TWO 2-22-42 666000112 Enrollment Priority: Category: IN PROCESS		ACTIVE DUTY
DEVICE: HOME// ;;999 ANYWHERE		
ACTIVE ALLERGY/ADVERSE REACTION LIST Run Date/Time: 6/25/04 11:56:58 am		
	1942 (62)	
		OBS/
ADVERSE REACTION	VERIFIED	HIST
TYPE: DRUG		
======================================	VEC	III CM
ALLENT ALUMINUM ACETATE	YES YES	HIST HIST
Reactions: CHILLS (Nov 25, 2002)	120	11101
AMOXICILLIN	NO	HIST
AMPICILLIN	NO	HIST
BILBERRY	YES	HIST
CANDESARTAN	YES	HIST
CARAMEL	YES	HIST
Reactions: HIVES (Jan 22, 1998),		
ITCHING, WATERING EYES (Jan 22, 1998)		07.0
CORICIDIN TAB	YES	OBS
Reactions: CHILLS, HYPOTENSION, NAUSEA, VOMITING	VEC	III OM
CORN STARCH CORRECTOL	YES YES	HIST HIST
CORTICOTROPIN	YES YES	HIST
CORTICOTROPIN/ZINC HYDROXIDE	YES	HIST
EYE WASHES/LUBRICANTS	NO	OBS
Reactions: DROWSINESS	NO	OBS
FILGRASTIM	YES	HIST
HAYFEBROL SF	NO	HIST
Reactions: ITCHING, WATERING EYES	1.0	
LOMEFLOXACIN	YES	OBS
Reactions: ITCHING, WATERING EYES (Mar 10, 1999)		
OXYCODONE	YES	HIST
PENICILLINS	NO	HIST
PENTAMIDINE	YES	HIST
PENTAZOCINE	YES	HIST
PENTETIC ACID	YES	HIST

RANITIDINE	YES	OBS
Reactions: CHILLS (Nov 26, 2002@11:16)		
TACRINE	YES	HIST
TAPE	YES	HIST
TAVIST	NO	HIST
TAVIST	NO	HIST
WARFARIN	YES	HIST
WATER	NO	HIST
ZANTAC	YES	HIST
TYPE: DRUG, FOOD		
CHOCOLATE	VEC	шташ
FLUPHENAZINE DECANOATE	YES NO	HIST
PEANUT OIL	NO NO	HIST OBS
Reactions:	NO	OBS
ITCHING, WATERING EYES (Oct 05, 2000@24:00),		
ANXIETY (Oct 06, 2000@09:27)		
SHELL FISH	NO	HIST
	2.0	11101
TYPE: FOOD		
=======		
NUTS	YES	HIST
Reactions: HIVES (Jan 02, 1998)		
PEACHES	YES	HIST
STRAWBERRIES	YES	HIST
TYPE: OTHER		
========		
	VEC	нтст
Enter RETURN to continue or '^' to exit:	1110	11101
DUST Enter RETURN to continue or '^' to exit:	YES	HIST

#### Print Patient Reaction Data

This option allows you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Data
Select PATIENT: ARTPATIENT, ONE 10-12-69 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1
DEVICE: HOME// < Enter> HYPER SPACE
ARTPATIENT, ONE 666-00-0111 REPORTS
                ALLERGY/ADVERSE REACTION REPORTS
                                         FEB 22,1942 (62)
STATUS: ACTIVE
 TYPE: DRUG
 ========
       AGENT: ALLENT
  INGREDIENTS: PSEUDOEPHEDRINE
                                VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
             BROMPHENIRAMINE
   ORIGINATOR: ARTPROVIDER, TWO
                                           ORIGINATED: MAR 17, 2004@14:34
     SIGN OFF: YES
                                           OBS/HIST: HISTORICAL
                                       CHART MARKED: MAR 17, 2004@14:34:16
TD BAND MARKED:
    MECHANISM: ALLERGY
Enter RETURN to continue or '^' to exit:
ALLERGY/ADVERSE REACTION REPORTS
                                          FEB 22,1942 (62)
```

VERIFIED: MAR 17, 2004@14:34:17 VERIFIER: AUTOVERIFIED 

AGENT: ALUMINUM ACETATE

INGREDIENTS: ALUMINUM ACETATE VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER, ONE ORIGINATED: NOV 26, 2002@11:25

OBS/HIST: HISTORICAL SIGN OFF: YES

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: CHILLS (Nov 25, 2002)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED VERIFIED: NOV 26, 2002@11:26:27

Enter RETURN to continue or '^' to exit:

ALLERGY/ADVERSE REACTION REPORTS Run Date/Time: 7/2/04 9:18:55 am

ARTPATIENT, ONE 666-00-0111 FEB 22,1942 (62)

AGENT: AMOXICILLIN

VA DRUG CLASSES: PENICILLINS, AMINO DER INGREDIENTS: AMOXICILLIN

ORIGINATOR: ARTPROVIDER, TWO ORIGINATED: JAN 21, 1998@10:20

SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

AGENT: AMPICILLIN

VA DRUG CLASSES: INGREDIENTS: AMPICILLIN

Enter RETURN to continue or '^' to exit:

ALLERGY/ADVERSE REACTION REPORTS Run Date/Time: 7/2/04 9:18:55 am

ARTPATIENT, ONE 666-00-0111 FEB 22,1942 (62)

ORIGINATOR: ARTPROVIDER, ONE ORIGINATED: JAN 21, 1998@10:25

SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

#### Print an FDA Report for a Patient

This option allows you to print an individual FDA report for a patient. This option will produce a listing of all allergy/adverse reactions that are awaiting sign off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```
Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT, TWO 12-01-34 6660001112 SC VETERAN
Select CAUSATIVE AGENT: ??
CHOOSE FROM:
  AMPICILLIN
  CYCLOSPORINE
  GENTAMICIN
   PENICILLIN
Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
  AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
     ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.
OUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)
Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
```

MEDWatch			App	roved by FDA	on 10/20/93	
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM			   Tr	Triage unit sequence #		
THE PDA MEDICAL PRODUCTS REPORTING PROGRAM				rage anne be	quence "	
	Page :	1 of 1				
A. Patient Information		C. Suspect Medication(s)				
1. Patient Indentifier 2. DOB: 12	/1/34  3. Sex 4. Weight					
T0112   AGE: 61 yrs  FÉMALE  0.0	····		AMPICILLIN	····	**********	
************************	*******		^^^^	^^^^	*************	
B. Adverse Event or Product Probl	em					
1. [X]Adverse Event [ ]Product pr	oblom	2 Dog			3 Thorany dates	
1. [A]Adverse Event [ ]Froduct pr	optem	2. Dose, frequency & route used #1:			#1 :	
2. Outcomes attributed to adverse	event					
[ ] death: [ ] disabili [ ] life-threatening [ ] congenit				I		
[] Hospitalization [] required		4.Diagnosis for use(indication		indication)	15. Event abated after use	
initial or prolonged prevent impa					stopped or dose reduced?	
[X] other		#1: #1		I	#1: [N/A]	
3. Date of event	4. Date of this report					
	01/30/96					
5. Describe event or problem		6. Lot	# (if known)	7. Exp. dat	e 8. Event reappeared after reintroduction	
RASH		#1:		#1:	#1: []	
		9. (Not applicable to adverse drug event reports)				
<ol><li>Relevant test/laboratory data. treatment)</li></ol>	including dates	10. Concomitant medical products/therapy dates(exclude				
creatment)						
		D. Suspect Medical Devices				
7. Other relevant History, including preexisting medical conditions		Note: Please use the actual MedWatch form if the event				
		involves a suspected device as well as a suspect drug				
		E. Reporter				
			1			

		1. Name, address & pho	ne #:	
=======================================				
Mail to: MedWatch	or FAX to:			
5600 Fishers Lane Rockville, MD 20852-9787	1-800-FDA-0178	2. Health professional	? 3. Occupation	4. Reported to Mfr. [NO]
		5. If you don't want y	our identity disc	losed to the
Manufacturer,			_	
		place an "X" in the box. [ ]		
FDA Form 3500				
		=		
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.				

#### Print all FDA Events Within D/T Range

This report prints all the FDA reports over a given date range, entered by you. You may choose to print Complete FDA Adverse Event Reports or an abbreviated listing of reports. Complete reports should be queued to a printer that has 132-column width. An abbreviated listing may be sent to a printer or CRT. If an abbreviated listing is chosen and if the report has been sent to the FDA, the listing will display the date that the report was sent.

```
Select Reports Menu Option: 4 Print All FDA Events within D/T Range
Select Start Date/Time: T-30 (JUN 07, 2004)
Select End Date/Time: (6/7/2004 - 7/7/2004): T// <Enter> (JUL 07, 2004)
Do you want an Abbreviated report? Yes// <Enter> (Yes)
DEVICE: HOME//<Enter>
                          ANYWHERE
Jul 07, 2004@07:38:46
                                                                 Page: 1
                               FDA ABBREVIATED REPORT
PATIENT
                               SUSPECTED AGENT
                                                                D/T OF EVENT
ARTPATIENT,ONE (666-00-0111) ANTIRABIES SERUM ARTPATIENT,TWO (666-00-0112) ANTIRABIES SERUM ARTPATIENT,THREE(666-00-0113) SHRIMP
                                                                Jun 8,2004
                                                               Jun 8,2004@12:15
                                                               Jun 15,2004
ARTPATIENT, FOUR (666-00-0114) ZANAMIVIR
                                                               Jun 21,2004
ARTPATIENT, FOUR (666-00-0114) ACYCLOVIR
                                                               Jun 21,2004
ARTPATIENT, FOUR (666-00-0114) RANITIDINE
                                                               Jun 21,2004
ARTPATIENT, FOUR (666-00-0114) ZANAMIVIR
                                                               Jun 21,2004@08:27
                                                               Jun 28,2004
ARTPATIENT, FIVE (666-00-0115) SHRIMP
                                                               Jun 30,2004
ARTPATIENT, FIVE (666-00-0115) FLOXURIDINE
                                                                Jun 30,2004
ARTPATIENT, FIVE (666-00-0115) FORMOTEROL
ARTPATIENT, FIVE (666-00-0115)
                                 FORMALDEHYDE
                                                                Jun 30,2004
Enter RETURN to continue or '^' to exit: <Enter>
```

#### Print Patient FDA Exception Data

This option allows you to print a list of all observed or drug allergies from a given date to the present for a patient that has been signed off (completed), but is missing sign/symptom data. You select a patient and the date from which to start the search.

The header of the report contains the name of the report and the date/time that it was run. The body contains the patient's name, SSN, the causative agent, the origination date/time of the entry and name of the originator.

```
Select Reports Menu Option: 5 Print Patient FDA Exception Data
                                                                    666000111
Select PATIENT NAME: ARTPATIENT, ONE ARTPATIENT, ONE
                                                         2-22-42
YES
      ACTIVE DUTY
Enrollment Priority:
                               Category: NOT ENROLLED End Date: 07/06/2004
Enter the Date to start search (Time optional): T-30//t-60 (MAY 08, 2004)
DEVICE: HOME// <Enter>
                         ANYWHERE
Jul 7,2004 07:42:26
                                                             Page: 1
                 FDA EXCEPTION REPORT (Starting at 5/8/04)
                  CAUSATIVE AGENT ORIGINATOR
ORIGINATION D/T
    Patient: ARTPATIENT, ONE (666-00-0111)
Jun 30,2004@10:31 FLOXURIDINE
                                                ARTPROVIDER, ONE
Jun 30,2004@10:34 FORMOTEROL
                                                ARTPROVIDER, ONE
Jun 30,2004@10:39 FORMALDEHYDE
                                                ARTPROVIDER, ONE
Enter RETURN to continue or '^' to exit: <Enter>
```

#### Print all FDA Exceptions within a D/T Range

This option allows you to select a date range from which to print a list of all patients who had an Observed Drug Reaction that has not been reported to the FDA. The report can be sent to a printer or to your terminal screen. The header of the report contains the name of the report, the date range selected by you and the date/time that the report was run. The body of the report contains the patient's name and SSN, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

```
Select Reports Menu Option: 6 Print All FDA Exceptions within a D/T Range
Select Start Date: T-90 (APR 08, 2004)
Select End Date: (4/8/2004 - 7/7/2004): T// <Enter> (JUL 07, 2004)
DEVICE: HOME// <Enter>
                         ANYWHERE
Jul 7,2004 07:37:28
                                                              Page: 1
                  FDA EXCEPTION REPORT (4/8/04 to 7/7/04)
ORIGINATION D/T
                  CAUSATIVE AGENT ORIGINATOR
     Patient: ARTPATIENT, ONE (666-00-0111)
Jun 8,2004@12:21 ANTIRABIES SERUM
                                                 ARTPROVIDER, ONE
     Patient: ARTPATIENT, TEN (666-00-0110)
Jun 8,2004@12:15 ANTIRABIES SERUM
                                                 ARTPROVIDER, ONE
     Patient: ARTPATIENT, TWO (666-00-0112)
Jun 30,2004@10:31 FLOXURIDINE Jun 30,2004@10:34 FORMOTEROL
                                                  ARTPROVIDER, ONE
                                                  ARTPROVIDER, TWO
Jun 30,2004@10:39 FORMALDEHYDE
                                                  ARTPROVIDER, THREE
     Patient: ARTPATIENT, THREE (666-00-0113)
Jun 16,2004@08:27 SHRIMP
                                                  ARTPROVIDER, ONE
    Patient: ARTPATIENT, FOUR (666-00-0114)
Apr 30,2004@09:33 PENICILLIN
                                                  ARTPROVIDER, ONE
    Patient: ARTPATIENT, FIVE (666-00-0115)
May 20,2004@12:09 LEAD ACETATE PURIFIED POWDER ARTPROVIDER, FOUR
Jun 21,2004@08:23 ZANAMIVIR
                                                  ARTPROVIDER, ONE
Jun 21,2004@08:38 ACYCLOVIR
                                                  ARTPROVIDER, FOUR
Jun 21,2004@09:43 RANITIDINE
                                                  ARTPROVIDER, TWO
Enter RETURN to continue or '^' to exit: <Enter>
```

### List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Reports Menu Option: 7 List by Location of Unmarked ID Bands/Charts

1 Current Inpatients
2 Outpatients over Date/Time range
3 New Admissions over Date/Time range
4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): t-90 (APR 08, 2004)
Enter END Date (time optional): T// <Enter> (JUL 07, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

Jun 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Mar 30,2004 TO Jun 28,2004@24:00			PAGE 1
PATIENT	SSN	ALLERGY	UNMARKED
	: 1A(1&2)		
ARTPATIENT, ONE		DAVE DRUG	TD BAND/CHART
Intiliii Ibiti / Oitb	000 00 0111		ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
		ASPIRIN	
		CHOCOLATE	
		MILK OF MAGNESIA	
		AMOXICILLIN	
		PENICILLIN	
		MENTHOL	ID BAND/CHART
ARTPATIENT, TWO	666-00-0112	AMOXICILLIN	ID BAND/CHART
		DUST	
		ZANTAC	ID BAND/CHART
ARTPATIENT, THR	EE 666-00-0113	CEPHALEXIN TABLETS,	ID BAND/CHART
Enter RETURN t	o continue or '^' to exit:		
Jun 28,2004	PATIENTS WITH UNMARK	KED ID BAND/CHART	PAGE 2
	CURRENT INPATIENTS / OUTPAT	TIENTS / NEW ADMISSIONS	
	FROM Mar 30,2004	TO Jun 28,2004@24:00	
PATIENT	SSN	ALLERGY	
		CHEESE	ID BAND/CHART
		BARIUM SULFATE	ID BAND/CHART

		OPIOID ANALGESICS	ID BAND/CHART
		RADIOLOGICAL/CONTRAS	ID BAND/CHART
		FOLIC ACID	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
		PENICILLIN	ID BAND/CHART
Jun 28,2004	PATIENTS WITH UNMARKED	ID BAND/CHART	PAGE 3
Cī	URRENT INPATIENTS / OUTPATIE	NTS / NEW ADMISSIONS	
	FROM Mar 30,2004 T	O Jun 28,2004@24:00	
PATIENT	SSN	ALLERGY	UNMARKED
		ACETANILIDE	ID BAND/CHART
		ANTIRABIES SERUM	ID BAND/CHART
ARTPATIENT, FOUR	666-00-0114	STRAWBERRIES	ID BAND/CHART
ARTPATIENT, FIVE	666-00-0115	CHOCOLATE	ID BAND/CHART
		BLUE CROSS AMPICILLI	ID BAND/CHART
		ACETAMINOPHEN TAB	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
Enter RETURN to o	continue or '^' to exit:		

#### Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by users entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO// <Enter>
DEVICE: HOME// < Enter> HYPER SPACE
                 ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                      Run Date/Time: 6/28/04 9:18:26 am
ORIGINATOR
                        PATIENT
                                            ALLERGY
                                                            ORIGINATION
DATE/TIME
PROVIDER, ONE ARTPATIENT, ONE (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER, ONE ARTPATIENT, ONE (0111) FROG FEB 18, 2003@15:14
PROVIDER, ONE ARTPATIENT, ONE (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER, ONE ARTPATIENT, TWO (0112) PENICILLIN JUN 22, 2003@11:44
PROVIDER, ONE ARTPATIENT, TWO (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER, ONE ARTPATIENT, TWO (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER, ONE ARTPATIENT, TWO (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER, ONE ARTPATIENT, TWO (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER, ONE ARTPATIENT, TWO (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER, ONE ARTPATIENT, TWO (0112) CODEINE JUN 30, 2003@08:55
PROVIDER, ONE ARTPATIENT, TWO (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER, ONE ARTPATIENT, TWO (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER, ONE ARTPATIENT, THREE (0113) CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER, ONE ARTPATIENT, THREE (0113) SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER, ONE ARTPATIENT, THREE (0114) DUCK JAN 06, 2004@11:13
Enter RETURN to continue or '^' to exit: ^
```

#### List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of Undocumented Allergies

1 Current Inpatients
2 Outpatients over Date/Time range
3 New Admissions over Date/Time range
4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??
    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
  Choose from:
   1 DR'S CLINIC
   13A PSYCH
   1A(1&2)
   2B MED
   8E REHAB MED
   8W SUBSTANCE ABUSE
   CARDIOLOGY
   CT ROOM
Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...
```

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1

CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS

FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT PROVIDER SSN

\_\_\_\_\_\_

WARD: 1A(1&2)

ARTPATIENT, ONE 666-00-0111 ARTPROVIDER, ONE

ARTPATIENT, TWO 666-00-1112P

ARTPATIENT, TWO 666-00-1112

ARTPROVIDER, TWO

Room/Bed: B-2

ARTPATIENT, THREE 666-12-4443 ARTPROVIDER, THREE

Room/Bed: 9-B

ARTPATIENT, FOUR 666-00-1114 ARTPATIENT, FIVE 666-00-1115 Enter RETURN to continue or '^' to exit:

PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2 Jul 2,2004

> CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT SSN PROVIDER

WARD: 2B MED

ARTPATIENT, SIX 666-00-1116 ARTPROVIDER, FOUR ARTPATIENT, SEVEN 666-00-1117

ARTPATIENT, SEVEN 666-00-1117 Enter RETURN to continue or '^' to exit:

PAGE 3 Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES

CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT SSN

\_\_\_\_\_\_

CLINIC: CARDIOLOGY

ARTPATIENT, EIGHT 666-00-1118 ARTPROVIDER, FIVE

ARTPATIENT, NINE 666-00-1119 ARTPATIENT, TEN 666-00-1110 Enter RETURN to continue or '^' to exit:

#### List Autoverified Reaction Data

This option lists autoverified reaction data by date/time range, location, and mechanism. It also displays previous sorting values that were used during this session. The first time that you run the report during this session, those previous values will be "not null." If you run the option again, the previous sorting values will display (e.g., \*Previous Selection: Verification Date/Time from 1/1/96 to 1/31/96@24:00).

The header of this report contains the name of the report, the date it was run, and the date range entered. The body of the report contains the data sorted, first by ward location, then by mechanism, and finally by verification date. The report contains the patient's name, the last digits in the SSN, room-bed, the causative agent, the signs/symptoms, the name of the person who originated the entry and any comments entered by the originator.

```
Select Reports Menu Option: 10 List Autoverified Reaction Data
* Previous selection: VERIFICATION DATE/TIME from Feb 1,1996 to Feb
29,1996@24:00
START WITH VERIFICATION DATE/TIME: Feb 1,1996// <Enter> (FEB 01, 1996)
GO TO VERIFICATION DATE/TIME: Feb 29,1996// T (JUL 07,\ 2004)
      * Previous selection: PATIENT: WARD LOCATION equals 1S
     START WITH WARD LOCATION: 1S// 1A
     GO TO WARD LOCATION: 1S// 2B
          * Previous selection: MECHANISM equals A (ALLERGY)
         START WITH NATURE OF REACTION: A// <Enter> ALLERGY
         GO TO NATURE OF REACTION: A// <Enter> ALLERGY
DEVICE: <Enter> ANYWHERE Right Margin: 80// <Enter>
07/07/04 LIST OF AUTOVERIFIED ALLERGIES FROM 02/01/96 TO 07/07/04 Page: 1
                                   REACTANT
PATIENT
                         ROOM-BED
                                                                 VER. DATE
WARD LOCATION: 1A(1&2)
   MECHANISM: ALLERGY
ARTPATIENT, ONE (0001)
                                   BEEF
                                                               JAN 7,1999
 ORIGIN.: ARTPROVIDER, ONE
   SIGNS: NAUSEA, VOMITING
          DIFFICULTY SWALLOWING
COMMENTS: Testing ART/TIU interface.
ARTPATIENT, TWO (0002)
                                  STRAWBERRIES
                                                             MAY 7,2004
 ORIGIN.: ARTPROVIDER, TWO SIGNS: HIVES
 COMMENTS:
```

#### List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV. The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 11 List by Location Not Verified Reactions
DEVICE: HOME// <Enter>
                          ANYWHERE
Report Date: Jul 07, 2004
                                                                       Page: 1
                     List of Unverified Reactions by Ward Location
                                  Ward Location: 13A PSYCH
   Origination Date/Time
                                  Originator
                                                              Reaction
ARTPATIENT, ONE (666-00-0111)
   Jul 16, 2003@11:49
                              ARTPROVIDER, ONE
                                                       RANITIDINE
ARTPATIENT, TWO (666-00-0112)
                                                       STRAWBERRIES
   Jul 09, 1996@08:04
                              ARTPROVIDER, TWO
ARTPATIENT, THREE (666-00-0113)
   Jul 09, 1996@08:04
                              ARTPROVIDER, TWO
                                                       DUST
ARTPATIENT, FOUR (666-00-0114)
   Jul 09, 1996@08:04
                             ARTPROVIDER, TWO
                                                       FISH LIVER OIL
ARTPATIENT, FIVE (666-00-0115)
                      ARTPROVIDER, THREE ARTPROVIDER, THREE
  May 24, 1999@14:21
Jul 02, 1999@13:40
                                                       MILK
                                                       BERGAMOT
  Aug 20, 1999@09:27
                              ARTPROVIDER, THREE
                                                       RANITIDINE
Enter RETURN to continue or '^' to exit:
```

#### List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user-supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.

The header of the report contains the title, the date range selected, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option: List by Location and Date All Signed
Reactions
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)
DEVICE: HOME//<Enter>
                      ANYWHERE
One moment please...
Jul 06, 2004
           List all Signed Patient Reactions for Ward Location 1A(1&2)
              From Jan 08, 2004 to Jul 06, 2004@24:00
Date
                 Originator Type Causative Agent
         Patient: ARTPATIENT, SIX (666-00-0116)
                                              D HAYFEBROL SF
Jan 12, 2004@12:56 ARTPROVIDER,ONE
                                              D DIRITHROMYCIN
DF ANTIRABIES SERUM
Jun 11, 2004@15:25 ARTPROVIDER, TWO
Jun 08, 2004@12:15 ARTPROVIDER, THREE
          Patient: ARTPATIENT, SEVEN (666-00-0117)
Feb 26, 2004@11:29 ARTPROVIDER,ONE D ZANTAC
May 04, 2004@10:52 ARTPROVIDER, ONE
                                            D FORMALDEHYDE
May 04, 2004@10:55 ARTPROVIDER, ONE
                                                  CONTACT LENS WETTING
SOLN
May 04, 2004@10:56 ARTPROVIDER, ONE
                                             D
                                                  NICO 400
                                             DF
May 04, 2004@10:57 ARTPROVIDER, ONE
                                                 CORN
May 04, 2004@11:00 ARTPROVIDER, ONE
                                             DF BCG VACCINE
          Patient: ARTPATIENT, EIGHT (666-00-0118)
Feb 26, 2004@11:31 ARTPROVIDER, ONE
                                                  ZANTAC
          Patient: ARTPATIENT, NINE (666-00-0119)
Feb 05, 2004@10:51 ARTPROVIDER, TWO
                                                 STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

#### List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)
DEVICE: HOME//
                ANYWHERE
Report Date: Jul 06, 2004
                                                              Page: 1
                     Adverse Reaction Tracking Report
                        From: 1/8/04 To: 7/6/04
Patient
                                      Dates Related Reaction
ARTPATIENT, ONE
                              Obs DT: 1/27/04 DUST
(666-00-1111)
                              Trk DT: 1/27/04
                              ______
Loc: 1A(1&2)
                                0 Days Difference
Obs: ARTPROVIDER, ONE
                             Obs DT: 1/30/04 CHOCOLATE
Trk DT: 1/30/04
ARTPATIENT, TWO
(666-00-1112)
Loc: OUT PATIENT
Obs: ARTPROVIDER, ONE
                              0 Days Difference
                     Obs DT: 1/30/04 CHOCOLATE Trk DT: 1/30/04
ARTPATIENT, THREE
(355-67-1996)
Loc: 8E REHAB MED
Obs: ARTPROVIDER, ONE
                              0 Days Difference
                                               ZANTAC
ARTPATIENT, FOUR
                              Obs DT: 2/2/04
(666-00-0114)
                              Trk DT: 2/2/04
Loc: 1A(1&2)
Obs: ARTPROVIDER, ONE
                                0 Days Difference
Enter RETURN to continue or '^' to exit:
```

#### Edit Chart and ID Band

This option allows you to designate that a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking Verifier Menu Option: 4 Edit Chart and ID Band
Select Patient: ARTPATIENT, TWO 10-04-69 6660000112 SC VETERAN
CHOOSE FROM:
  ASPIRIN
  COD LIVER OIL
  DEMECARIUM
  FROGS
  PENBUTOLOL
  PENICILLIN
  PHENOBARBITAL
  PHENYTOIN
  PREDNISONE
  THOR - PROM
  TIMOLOL
  TYLOXAPOL
Select CAUSATIVE AGENT: ASPIRIN 10-04-69 6660000112 SC VETERAN
ASPIRIN
Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 6660000112
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
   PENICILLIN
   ASPIRIN
Has the ID Band been marked for this CAUSATIVE AGENT? Y (Yes)
```

## FDA Enter/Edit Menu (Verifier)

This menu should be given to people responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu will allow you to edit the FDA data.

- 1. Enter/Edit FDA Report Data
- 2. Enter/Edit P&T Committee Data

#### Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (e.g., Health Professional), whether the 15-day report was completed, and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data
Select PATIENT NAME: ARTPATIENT, ONE
                                        2-22-42 666000111 YES
                                                                          ACTIVE DUTY
Enrollment Priority: Category: NOT ENROLLED End Date: 07/06/2004
Select CAUSATIVE AGENT: FLOXURIDINE, PATIENT ARTPATIENT, ONE
                                                               2-22-42
                                                                            666000111
    YES ACTIVE DUTY
 Enrollment Priority:
                                 Category: NOT ENROLLED End Date: 07/06/2004
      FLOXURIDINE
Select date reaction was OBSERVED (Time Optional): 6/30/04 (JUN 30, 2004)
        ...OK? Yes// <Enter> (Yes)
Indicate which FDA Report Sections to be completed:

    Reaction Information
    Suspect Drug(s) Information
    Concomitant Drugs and History

4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): 1
The following is the list of reported signs/symptoms for this reaction:
          These reactions were entered by another user:
     Signs/Symptoms
     RASH
```

```
Select Action (A)DD OR <RET>: A
The following are the top ten most common signs/symptoms:
1. CHILLS
                                   7. HIVES
2. ITCHING, WATERING EYES
                                  8. DRY MOUTH
3. HYPOTENSION
                                   9. DRY NOSE
4. DROWSINESS
                                  10. RASH
5. NAUSEA, VOMITING
                                  11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 7
The following is the list of reported signs/symptoms for this reaction:
         These reactions were entered by another user:
    Signs/Symptoms
    HIVES
    RASH
Select Action (A)DD OR <RET>: <Enter>
Patient died?: N NO
Reaction treated with RX drug?: N NO
Life Threatening illness?: N NO
Required hospitalization?: N NO
Prolonged Hospitalization?: N NO
Resulted in permanent disability?: N NO
Is this event a Congenital Anomaly?: N NO
Did this event require intervention to prevent impairment/damage?: N NO
THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD
View Tx/Test from: JUN 30, 2004// <Enter> (JUN 30, 2004)
To: JUN 30, 2004//T (JUL 07, 2004)
LAB TEST:
  Collection DT Test Name
                                      Specimen
                                                  Results
                                                                  Hi/Low
    THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??
    You may enter a new RELEVANT TEST/LAB DATA, if you wish
Select TEST: ??
Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS, TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)
```

```
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
Select TEST: 1/2Hr.GTT (URINE)
 Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
CTION REPORTING)? No// Y (Yes)
 RESULTS: ??
       This field will contain the results for the particular test.
 RESULTS: Enter results here
 COLLECTION D/T: t (JUL 07, 2004)
Select TEST: <Enter>
This patient has the following Test selected:
TEST/TX
                               RESULTS
                                                              DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)
                               Enter results here
                                                              07/07/04
Select Action (A/D/E): <Enter>
Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): <Enter>
```

#### Enter/Edit P&T Committee Data

This option allows you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician. You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data
                                                   666000111
Select PATIENT NAME: ARTPATIENT, ONE
                                        2-22-42
                                                                YES
                                                                         ACTIVE DUTY
Enrollment Priority:
                                 Category: NOT ENROLLED End Date: 07/06/2004
Select CAUSATIVE AGENT: AMOXICILLIN, PATIENT ARTPATIENT, ONE 2-22-42 666000111
        ACTIVE DUTY
                                 Category: NOT ENROLLED End Date: 07/06/2004
 Enrollment Priority:
       AMOXICILLIN
Select date reaction was OBSERVED (Time Optional): JUNE 30, 2004 (JUN 30, 2004)
JUN 30, 2004 (JUN 30, 2004)
  Are you adding 'JUN 30, 2004' as
    a new ADVERSE REACTION REPORTING? No// Y (Yes)
P&T Report Completion
Serious ADR?: Y YES
ADR related to new drug? (Marketed within the last 2 yrs.): N NO
Unexpected ADR?: Y YES
ADR related to therapeutic failure?: N NO
Dose related?: N NO
P&T ACTION FDA REPORT: ??
        This field indicates if the P&T committee determined whether to send
        the report to FDA.
     Choose from:
               YES
       У
               NO
       n
P&T ACTION FDA REPORT: N NO
P&T ACTION MFR REPORT: N NO
ADDENDUM:
  1> <Enter>
Select PATIENT NAME: <Enter>
```

## P&T Committee Menu

The Patient & Therapeutic (P&T) Committee menu should be given to the P&T Committee members of Adverse Reaction Tracking, as designated by the site. The options on this menu allow you to edit P&T data and print FDA data. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070.

- 1. Enter/Edit P&T Committee Data
- 2. Enter/Edit FDA Report Data
- 3. Reports Menu ...

## **Enter/Edit P&T Committee Data**

This option allows you to edit P&T data. It allows for the evaluation of a suspected Advanced Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data
Select PATIENT NAME: ARTPATIENT, ONE
                                        2-22-42
                                                   666000111
                                                                        ACTIVE DUTY
                                                                YES
Enrollment Priority:
                                 Category: NOT ENROLLED End Date: 07/06/2004
Select CAUSATIVE AGENT: AMOXICILLIN, PATIENT ARTPATIENT, ONE
                                                               666000111
                                                                             YES
ACTIVE DUTY
                                 Category: NOT ENROLLED End Date: 07/06/2004
Enrollment Priority:
      AMOXICILLIN
Select date reaction was OBSERVED (Time Optional): JUNE 30, 2004 (JUN 30, 2004)
JUN 30, 2004 (JUN 30, 2004)
 Are you adding 'JUN 30, 2004' as
    a new ADVERSE REACTION REPORTING? No// Y (Yes)
P&T Report Completion
Serious ADR?: Y YES
ADR related to new drug? (Marketed within the last 2 yrs.): N NO
Unexpected ADR?: Y YES
ADR related to therapeutic failure?: N NO
Dose related?: N NO
P&T ACTION FDA REPORT: ??
        This field indicates if the P&T committee determined whether to send
        the report to FDA.
     Choose from:
      У
               YES
               NO
      n
P&T ACTION FDA REPORT: N NO
P&T ACTION MFR REPORT: N NO
ADDENDUM:
 1> <Enter>
Select PATIENT NAME: <Enter>
```

## **Enter/Edit FDA Report Data**

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data
                                                           YES
                                                                     ACTIVE DUTY
Select PATIENT NAME: ARTPATIENT, ONE
                                      2-22-42
                                                 666000111
Enrollment Priority: Category: NOT ENROLLED End Date: 07/06/2004
Select CAUSATIVE AGENT: FLOXURIDINE, PATIENT ARTPATIENT, ONE
                                                           2-22-42 666000111
       ACTIVE DUTY
Enrollment Priority:
                               Category: NOT ENROLLED End Date: 07/06/2004
      FLOXURIDINE
Select date reaction was OBSERVED (Time Optional): 6/30/04 (JUN 30, 2004)
        ...OK? Yes// <Enter> (Yes)
Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): 1
The following is the list of reported signs/symptoms for this reaction:
         These reactions were entered by another user:
    Signs/Symptoms
    RASH
```

```
Select Action (A)DD OR <RET>: A
The following are the top ten most common signs/symptoms:
                                   7. HIVES
1. CHILLS
2. ITCHING, WATERING EYES
                                  8. DRY MOUTH
                                  9. DRY NOSE
3. HYPOTENSION
4. DROWSINESS
                                  10. RASH
5. NAUSEA, VOMITING
                                  11. OTHER SIGN/SYMPTOM
6. DIARRHEA
Enter from the list above : 7
The following is the list of reported signs/symptoms for this reaction:
         These reactions were entered by another user:
    Signs/Symptoms
    HIVES
    RASH
Select Action (A)DD OR <RET>: <Enter>
Patient died?: N NO
Reaction treated with RX drug?: N NO
Life Threatening illness?: N NO
Required hospitalization?: N NO
Prolonged Hospitalization?: N NO
Resulted in permanent disability?: N NO
Is this event a Congenital Anomaly?: N NO
Did this event require intervention to prevent impairment/damage?: N NO
THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): ADD
View Tx/Test from: JUN 30, 2004// <Enter> (JUN 30, 2004)
To: JUN 30, 2004//T (JUL 07, 2004)
LAB TEST:
                                                  Results
  Collection DT Test Name
                                      Specimen
                                                                  Hi/Low
    THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.
Select TEST: ??
    You may enter a new RELEVANT TEST/LAB DATA, if you wish
Select TEST: ??
Choose from:
1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS, TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
```

```
2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
Select TEST: 1/2Hr.GTT (URINE)
 Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
CTION REPORTING)? No// Y
  (Yes)
  RESULTS: ??
        This field will contain the results for the particular test.
 RESULTS: Enter results here
 COLLECTION D/T: t (JUL 07, 2004)
Select TEST: <Enter>
This patient has the following Test selected:
TEST/TX
                                  RESULTS
                                                                   DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)
                                  Enter results here
                                                                   07/07/04
Select Action (A/D/E): <Enter>
Indicate which FDA Report Sections to be completed:
1. Reaction Information

    Suspect Drug(s) Information
    Concomitant Drugs and History

4. Manufacturer Information5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): <Enter>
```

## Reports Menu (P&T)

This option is the menu of all reports that the Pharmacy and Therapeutics Committee can print. To view data for options 1 thru 12 below, please see the Reports Menu under the Verifier Menu (see Table of Contents for correct page numbers.) For options 13 thru 19, please continue on the following pages.

- 1. Print an FDA Report for a Patient
- 2. Print all FDA Events within D/T range
- 3. Print Patient FDA Exception Data
- 4. Print all FDA Exceptions within a D/T range
- 5. Patient Allergies Not Signed Off
- 6. Print Patient Reaction Data
- 7. Active Listing of Patient Reactions
- 8. List by Location of Undocumented Allergies
- 9. List Autoverified Reaction Data
- 10. List by Location Not Verified Reactions
- 11. List by Location and Date all Sign Reactions
- 12. List FDA Data by Report Date
- 13. List of Fatal Reaction Over a Date Range
- 14. Print Summary of Outcomes
- 15. Frequency Distribution of Causative Agents
- 16. Frequency Distribution of Drug Classes
- 17. Total Reported Reactions Over a Date Range
- 18. P&T Committee ADR Outcome Report
- 19. P&T Committee ADR Report

#### List of Fatal Reaction Over a Date Range

This option lists all fatal adverse drug reactions over a selected date range.

The header of the report contains the name of the report, the date range selected, and the date that the report was printed. The body of the report contains the name of the patient, the last four digits of the patient's SSN, the date of the reaction, the name of the related reaction, and the date the patient died.

## **Print Summary of Outcomes**

This option prints a summary report of patient outcomes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the outcome and number of times a user answered with a "Yes, No or No Response" to the outcome question. A total is printed for each column of responses. The number of records processed is printed, also. The sum of each Yes, No, and No Response column equals the number of records processed (e.g., 3+38+249=290).

```
Select Reports Menu Option: 14 Print Summary of Outcomes
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
DEVICE: HOME// <Enter> ANYWHERE
Report Date: Jul 07, 2004
                                                     Page: 1
                         Summary of Outcomes
                    From: 7/8/03 To: 7/7/04
                                   Yes
                                              No
                                                     No Response
   ______
               Patients that Died:
                                            | 2 | 50
     Reactions treated with RX drugs:
                                                     | 50
          Life Threatening illness:
                                                     50
              Required ER/MD visit:
                                                     52
                                                     50
           Required hospitalization:
                                            2
                                                     50
          Prolonged Hospitalization:
                                            2
                                            2
                                                     | 50
     Resulted in permanent disability:
                                                      52
                Patient recovered:
                                                     | 50
                Congenital Anomaly:
                                                     | 50
              Required intervention:
                           Totals: 0 | 16 | 504
                  Total number of records processed 52
Enter RETURN to continue or '^' to exit: ^
```

## Frequency Distribution of Causative Agents

This option prints a report of the frequency distribution of causative agents for a date range selected by you.

The header of the report contains the name of the report, the date range selected by you and the date that the report was run. The body of the report contains the name of the causative agent and the number of times it was reported within the date range.

```
Select Reports Menu Option: 15 Frequency Distribution of Causative Agents
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
DEVICE: HOME// <Enter> ANYWHERE
Report Date: Jul 07, 2004
                                                          Page: 1
            Frequency Distribution of Causative Agents
From: 7/8/03 To: 7/7/04
Causative Agents
                  CHOCOLATE: 6
                 AMOXICILLIN: 3
                      DUST :
                  FILGRASTIM :
                  PENICILLIN :
                      ZANTAC :
                   ACYCLOVIR :
             ANTIRABIES SERUM :
               BACAMPICILLIN :
                  RANITIDINE :
                     SHRIMP :
                STRAWBERRIES :
                  ZANAMIVIR :
                  AMPICILLIN :
                   BENADRYL :
   BETA-LACTAM ANTIMICROBIALS: 1
Enter RETURN to continue or '^' to exit:
Report Date: Jul 07, 2004
                                                          Page: 2
             Frequency Distribution of Causative Agents
                   From: 7/8/03 To: 7/7/04
Causative Agents
                              Number
                   CAFFEINE :
              CORICIDIN TAB: 1
        EYE WASHES/LUBRICANTS :
                FLOXURIDINE :
                FORMALDEHYDE :
                  FORMOTEROL :
                  GREEN BEAN :
                     IODINE :
 LEAD ACETATE PURIFIED POWDER :
                  MENADIONE :
                   PARABEN:
                  PEANUT OIL :
    POLLEN ALLERGENIC EXTRACT :
        SHILEY TRACH TUBE CFS :
                    Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

## Frequency Distribution of Drug Classes

This option prints a report of the frequency distribution of drug classes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the drug classification name followed by its code in parentheses and the number of times it was reported during the selected date range.

```
Select Reports Menu Option: 16 Frequency Distribution of Drug Classes
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
DEVICE: HOME// ANYWHERE
Report Date: Jul 07, 2004
                                                         Page: 1
               Frequency Distribution of Drug Classes
                     From: 7/8/03 To: 7/7/04
                                  Number
______
PENICILLINS, AMINO DERIVATIVES (AM052) :
                                      6
          ANTIVIRALS (AM800):
       HISTAMINE ANTAGONISTS (GA301) :
     BLOOD FORMATION PRODUCTS (BL400):
PENICILLIN-G RELATED PENICILLI (AM051):
DERMATOLOGICALS, TOPICAL OTHER (DE900) :
               IMMUNE SERUMS (IM400):
           ANTIVIRAL, TOPICAL (DE103) :
   BETA-LACTAM ANTIMICROBIALS (AM100) :
ANTINEOPLASTICS, ANTIMETABOLITE (AN300):
    ANTISEPTICS/DISINFECTANTS (AS000):
   IMMUNOLOGICAL AGENTS,OTHER (IM900) :
        EYE WASHES/LUBRICANTS (OP500) :
 PHARMACEUTICAL AIDS/REAGENTS (PH000) :
BRONCHODILATORS, SYMPATHOMIMETI (RE102):
             SUPPLIES, OTHER (XA900):
  ANTIHISTAMINES, ETHANOLAMINE (AH102) :
                   MENADIOL (VT701) :
                    Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

## Total Reported Reactions Over a Date Range

This option prints a report of the total number of reported reactions for a selected date range.

The header of the report contains the title of the report and when it was run. The body of report contains the total number of actions reported for the date range listed.

```
Select Reports Menu Option: 17 Total Reported Reactions Over a Date Range
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)

DEVICE: HOME// ANYWHERE

Report Date: Jul 07, 2004 Page: 1
Reported Reactions

Total Number of Reported Reactions: 52
From: 7/8/03 To: 7/7/04
Enter RETURN to continue or '^' to exit:
```

#### P&T Committee ADR Outcome Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range and a summary of the listed outcomes for those ADRs. The header of this report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, whether the reaction required treatment (Req. Tx), whether the reaction required hospitalization (Req. Hosp), whether the reaction caused a permanent disability (Dis.), and did the patient die as a result of the reaction.

```
Select Reports Menu Option: 18 P&T Committee ADR Outcome Report
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
DEVICE: HOME// <Enter> ANYWHERE
Report Date: Jul 07, 2004
                                                         Page: 1
                  P&T Committee ADR Outcome Report
                     From: 7/8/03 To: 7/7/04
Obsv. | Req. | Req. | Req. | Date | Causative agent-Pat. ID | Sign/Symptoms | Tx | Hosp|Dis. | Death
______
7/16/03|BETA-LACTAM ANTIMICROB-C4573 |HYPOTENSION |
                                   ANAPHYLAXIS
7/16/03|RANITIDINE-F8839
                                   CHILLS
7/30/03 PARABEN-F0388
7/31/03|CHOCOLATE-W0167
 8/1/03|ACYCLOVIR-A2222
                                   CHILLS
 8/1/03|BENADRYL-F0388
                                   NAUSEA, VOMITING
                                   CHILLS
Enter RETURN to continue or '^' to exit:
Report Date: Jul 07, 2004
                                                         Page: 2
                  P&T Committee ADR Outcome Report
                    From: 7/8/03 To: 7/7/04
Obsv.
                                                   |Req.|Req.|
Date | Causative agent-Pat. ID | Sign/Symptoms | Tx | Hosp|Dis. | Death
8/19/03 CHOCOLATE-B5545
                                   CHILLS
8/21/03 DUST-J8910
                                   CHILLS
8/27/03 DUST-W1321
                                   CHILLS
8/27/03 SHILEY TRACH TUBE CFS-S4423 | CHILLS
8/28/03 CHOCOLATE-W1321
                                   DRY NOSE
8/28/03 GREEN BEAN-F8828
                                   CHILLS
8/28/03 STRAWBERRIES-A2222
                                   CHILLS
```

Enter RETURN to continue or '^' to exit:							
Report Date: Jul 07, 2004 Page: 3  P&T Committee ADR Outcome Report  From: 7/8/03 To: 7/7/04							
Obsv. Date	    Causative agent-Pat. ID			Req.		  Death	
8/28/03	   ZANTAC-A2222	ANXIETY	   	   	 	   	
8/28/03	  ZANTAC-W1321	ANXIETY	   	   	   	   	
9/17/03	  POLLEN ALLERGENIC EXTR-B8831	  HYPOTENSION	   	   	   	   	
11/4/03	  CAFFEINE-B8831	  RASH	   	   	   	   	
1/19/04	  EYE WASHES/LUBRICANTS-A4321	DROWSINESS	   	   	   	   	
1/27/04	  DUST-N5423 	  CHILLS	   	   	   	   	
1/30/04	  CHOCOLATE-B1996 	  CHILLS 	   	   	   	   	
Enter RE	   TURN to continue or '^' to exi	t:	l	I	I	I	
Report Date: Jul 07, 2004 Page: 4  P&T Committee ADR Outcome Report  From: 7/8/03 To: 7/7/04							
Obsv. Date	  Causative agent-Pat. ID	  Sign/Symptoms	Req.	Req.	  Dis.	  Death	
1/30/04	  CHOCOLATE-Z3431	CHILLS	   	   	·   	   	
2/2/04	  PENICILLIN-L7727	  ITCHING,WATERING EY	   	   	   	   	
2/2/04	   ZANTAC-N5423 	  CHILLS	   	   	   	   	
2/12/04	  AMOXICILLIN-Z4255 	CHILLS   DRY MOUTH	   	   	   	   	
2/18/04	  FILGRASTIM-Z3333	  CHILLS	   	   	   	   	
2/18/04	  FILGRASTIM-Z3333 	CHILLS ITCHING, WATERING EY	   	   	   	   	
Enter RETURN to continue or '^' to exit:							
Report Date: Jul 07, 2004 Page: 5  P&T Committee ADR Outcome Report  From: 7/8/03 To: 7/7/04							
Obsv. Date	  Causative agent-Pat. ID			Req.			
2/19/04	AMOXICILLIN-Z4255	HYPOTENSION	   	   	   	   	
2/19/04	  PENICILLIN-Z4255	  CHILLS	   	   	   	   	
2/26/04	  FILGRASTIM-Z6414 	  CHILLS  FREE TEXT	   	   	   	    -	
2/26/04	  MENADIONE-Z8322	  CHILLS	 	 	 	 	

		FREE TEXT 	 	 	 	 
2/27/04	  BACAMPICILLIN-B8849 	  DIARRHEA 	   	   	   	   
2/27/04	  BACAMPICILLIN-Z4255 	  DIARRHEA 	   	   	   	
Enter RE?	TURN to continue or '^' to exi	t:	I	ı	I	I
Report Date: Jul 07, 2004 Page: 6 P&T Committee ADR Outcome Report From: 7/8/03 To: 7/7/04						
Obsv. Date	  Causative agent-Pat. ID			Req.		  Death
3/16/04	CHOCOLATE-A0150	DROWSINESS NAUSEA, VOMITING DIARRHEA	     	     	     	     
3/16/04	  PEANUT OIL-A0150   	HYPOTENSION DIARRHEA DRY MOUTH	     	     	     	
3/17/04	  CORICIDIN TAB-A4321   	  CHILLS  HYPOTENSION 	     	     	     	     
4/2/04	  AMPICILLIN-A8989 	  CHILLS			   	
	  STRAWBERRIES-A8989  TURN to continue or '^' to exi	  CHILLS 				
Report Date: Jul 07, 2004 Page: 7  P&T Committee ADR Outcome Report  From: 7/8/03 To: 7/7/04						
Obsv. Date	  Causative agent-Pat. ID			Req.		    Death 
4/30/04	  PENICILLIN-D6616	  HIVES	 	 	 	
5/20/04	  IODINE-B8847	DRY NOSE	 	 	 	 
5/20/04	  LEAD ACETATE PURIFIED -Z9558	  HIVES	   	   	   	   
6/8/04	  ANTIRABIES SERUM-H2591 	  CHILLS 	   	   	   	   
6/8/04	  ANTIRABIES SERUM-A0999 	  CHILLS 	   	   	   	   
6/15/04	  SHRIMP-T8828	  HIVES	İ			
1, 20, 01	İ		1	1	j	
6/21/04	  ACYCLOVIR-Z9558  TURN to continue or '^' to exi	HYPOTENSION t:	 		<u> </u>	
6/21/04 Enter RET		t: R Outcome Report	]	   Page:	8	
6/21/04 Enter RET Report Da	TURN to continue or '^' to exi ate: Jul 07, 2004 P&T Committee ADI	t:  R Outcome Report  Fo: 7/7/04	  Req.  Tx	  Req.	· 	        Death

6/21/04	  ZANAMIVIR-Z9558	  CHILLS	 		 		
6/21/04	  ZANAMIVIR-Z9558 	  CHILLS  HYPOTENSION	   		   	   	
6/28/04	  SHRIMP-A4321 	  RASH	   		   	    -	
6/30/04	  AMOXICILLIN-A4321				! !		
6/30/04	  FLOXURIDINE-A4321 	  RASH  HIVES	   		   	   	
Enter RETURN to continue or '^' to exit:							
Report Date: Jul 07, 2004 Page: 9 P&T Committee ADR Outcome Report From: 7/8/03 To: 7/7/04							
Obsv. Date	    Causative agent-Pat. ID			Req.		    Death	
6/30/04	    FORMALDEHYDE-A4321	    RASH	   		   	   	
6/30/04	  FORMOTEROL-A4321	  RASH	 		 	[ ]	
	1 01010111011 111311	1	1	1	:	i	

## P&T Committee ADR Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range. The Sign/Symptoms, Mechanism, Severity, and Comments are displayed for each ADR. This report should be queued to a printer that has a column width of 132 characters. The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, the mechanism of the adverse reaction (i.e., A=Allergy, P=Pharmacologic, and U=Unknown), and any comments entered. The comments are identified by category (i.e., Observer, Verifier or Entered in Error).

```
Select Reports Menu Option: 19 P&T Committee ADR Report
Select an Observed date range for this report.
Enter Start Date: 1/1/96 (JAN 01, 1996)
Enter Ending Date: 1/31/96 (JAN 31, 1996)
This report required a 132 column printer.
DEVICE: HOME// QUEUE TO PRINT ON
DEVICE: HOME// SELECT APPROPRIATE PRINTER COMPUTER ROOM
Requested Start Time: NOW// < Enter> (FEB 06, 1996@11:23:22)
Request queued...
                     Report Date: Feb 06, 1996 Page: 1
                        P&T Committee ADR Report
                        From: 1/1/96 To: 1/31/96
Obsv.
                                                     LADR LADR
                                                          |Svr. | Comments
       Causative agent
                              |Sign/Symptoms
                                                    Mech
Date
                                                                OBSERVER COMMENTS:
1/1/96 | PSUEDOEPHEDRINE
                              LHIVES
                                                     TT
                               ITCHING. WATERING EY
                                                                THIS IS A TEST
                               NAUSEA, VOMITING
                               DIARRHEA
                               ANXIETY
                               CHILLS
                               DROWSINESS
                               DRY MOUTH
                               HYPOTENSION
1/8/96
       SALT SUBSTITUTE
                               SWELLING (NON-SPECI
                                                     IJ
                                                           MOD. OBSERVER COMMENTS:
                               NAUSEA, VOMITING
                                                                Patient's swelling
                                                                was observed by the
                                                                nurse.
1/8/96
       FUZZEL
                                                     U
                                                                OBSERVER COMMENTS:
                               ITCHING, WATERING EY
                               NAUSEA, VOMITING
                               DIARRHEA
1/9/96 | POLLEN
                               ITCHING, WATERING EY
                                                     U
                                                           MOD. OBSERVER COMMENTS:
                                                                the patient had a
                                                                moderate reaction
                                                                to some flowers.
1/10/96 ASPIRIN
                               NAUSEA, VOMITING
                                                     U
                               DRY MOUTH
```

## Using ART in CPRS GUI

### On the Cover Sheet

In the Allergies/Adverse Reactions pane on the Cover Sheet tab, CPRS displays a list of causative agents associated with patients' allergies or adverse reactions. If patients have causative agents listed in this pane, CPRS also displays the word *Allergies* in the Postings pane and the letter **A** (for allergies) on the Postings button. To view more information about allergies or adverse reactions associated with the causative agents listed in the Allergies/Adverse Reactions pane, simply click on the causative agent in which you are interested. CPRS then displays a comprehensive listing of the details associated with this causative agent.

You can obtain less comprehensive information about allergies and adverse reactions by clicking the word *Allergies* in the Postings pane. When you do this, CPRS displays information about the causative agents, severity, and signs/symptoms associated with patients' allergies and adverse reactions.

From the Cover Sheet tab, you can also:

- Enter new allergies
- Mark existing allergies or adverse reactions as having been entered in error
- Enter no-known-allergies (NKA) assessments

## **Entering Allergies from the Cover Sheet**

You can enter a new allergy or adverse reaction from the Cover Sheet tab in either of two ways:

- Right-click anywhere within the Allergies/Adverse Reactions pane.
- Click to display more information about a causative agent listed in the Allergies/Adverse Reactions pane.

#### Method One

Follow these steps to enter new allergies using the first of the two methods mentioned above:

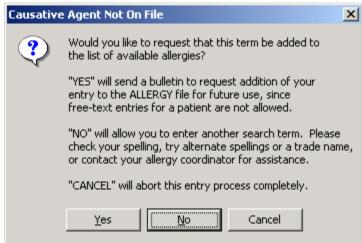
- 1. Move your mouse arrow to a location anywhere within the Allergies/Adverse Reactions pane.
- 2. Right-click to display a pop-up menu.
- 3. From this menu, select Enter new allergy. CPRS displays the Allergy Reactant Lookup dialog.

**Note:** Many new synonyms have been added to the ALLERGY REACTANT file #120.82, as part of data standardization. When you open the Allergy Reactant Lookup window and enter three characters for a causative agent, you might see a list of matches such as this:

(The new synonyms are the ones in the <> brackets) Allergy Reactant Lookup Enter causative agent for Allergy or Adverse Drug Reaction: (Enter at least 3 characters) soy Search Select from one of the following items 19 matches found. SOY SOY MILK SOY PRODUCTS SOY SAUCE SOYBEAN OIL SOYBEANS SOYBEAN OIL (SOY BEAN OIL) SOYBEANS (SOY BEANS) SOY SAUCE <SOY SAUCES> SOYBEANS (SOYA) SOY (SOYS) SOYBEANS (SOYS BEANS) SOY SAUCE <SOYS SAUCES> ⊕ 
 ✓ National Drug File - Generic Drug Name (1). National Drug file - Trade Name (3). ■ No Known Allergies OK Cancel Select from the matching entries on the list, or search again.

- 4. In the Enter causative agent for Allergy or Adverse Drug Reaction field, type the first three characters (minimum) of the causative agent's name.
- 5. Click Search. CPRS displays a list of possible matches.
- 6. If the causative agent you typed does not match any of the agents currently available, CPRS displays the Causative Agent Not On File dialog, from which you can select one of the following three options:

**Note:** The patient's chart will not be updated unless you choose a causative agent that is on file.



- a. Yes: Use this option to request that the causative agent be added to the ALLERGY REACTANT file. When you click Yes, CPRS displays the Enter Optional Comments dialog, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or whether you observed these symptoms firsthand. After you type your comments, click Continue. CPRS then sends to your site's mailgroup a message that includes the following items:
  - The causative agent you attempted to enter
  - The name of the patient for whom you attempted to make this entry
  - Your name, title, and contact information
  - Your comments (if any)

Members of your mailgroup will review this message and, if appropriate, will enter the agent in the NTRT system, so that it can add the causative agent to the ALLERGY REACTANT file for all sites.

**Note:** If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:

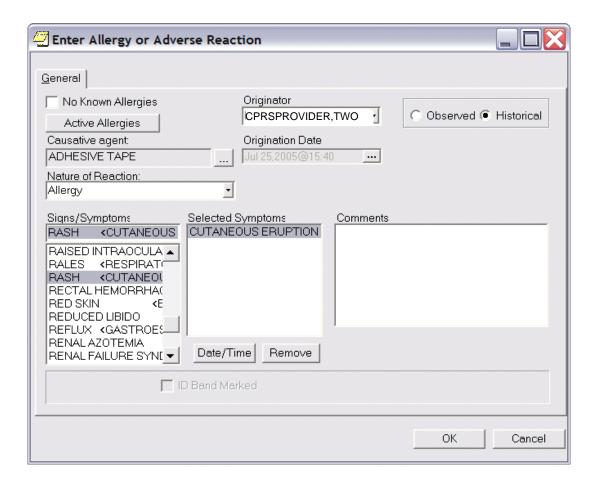


- b. **No**: Clicking No enables you to try an alternate spelling or trade name for your causative agent, or to type another causative agent.
- c. Cancel: Use this option if you want to cancel your allergy entry.
- 7. If the causative agent you typed matches an agent that is currently available, select the agent. (Click + to expand a heading.)

**Note:** With CPRS GUI 24 or later, you may not add free-text causative agents. If you select an item under the "Add new free-text allergy" heading, CPRS displays the *Causative Agent Not On File* dialog. (See Step 6 above.)

8. Click OK. The Enter Allergy or Adverse Reaction dialog appears.

**NOTE:** Synonyms appear now in <> brackets.



**Note**: You can view a patient's current allergies or adverse reactions by clicking the Active Allergies button.

- 9. Using the Originator box, select an originator.
- 10. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (If you point your mouse at either of these option buttons, CPRS displays a hover hint that defines observed and historical.)

**Note:** CPRS does not allow you to select future dates for observed allergy/adverse reaction entries.

**Note:** When you select Observed for a drug reaction, CPRS generates a Progress Note. Once this note is signed by the user entering the allergy or by an administrative update user, the note will be viewable by all users.

11. Select the Nature of Reaction (Allergy, Pharmacological, or Unknown).

The Nature of Reaction can be Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. Unknown is provided if you are not sure what Nature of Reaction (mechanism) to enter.

**Note**: Allergies are a subset of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

- 12. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity box is not visible for historical allergies. If the Severity box is visible, CPRS displays a ? button at its side. If you click this button, CPRS displays text explaining severity selections.)
- 13. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.
- 14. To associate a date and time with a symptom (optional), click to select the symptom in the Selected Symptoms pane.
- 15. Click the Date/Time button located below the Selected Symptoms pane. CPRS displays the Select Date/Time dialog, from which you can select the date and time that the symptom first appeared.

**Note:** If you mistakenly enter a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the Selected Symptoms pane and click the Remove button located beneath the pane.

- 16. Type comments for the allergy in the Comments box.
- 17. If you have marked the allergy or adverse reaction on the patient's identification (ID) band (or if you know that someone else has), select the ID Band Marked checkbox.

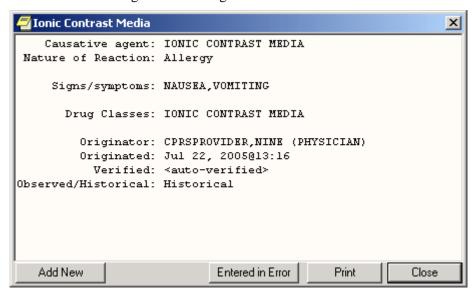
**Note:** CPRS activates the ID Band Marked checkbox only for inpatients and then only if your site's IRM staff has set a parameter indicating that your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do *not* select activated ID Band Marked checkbox, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

18. Click OK. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter **A** (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If you click the word *Allergies* in the Postings pane, CPRS displays selected information about all of the patient's active allergies and adverse reactions, including the allergy or adverse reaction you just entered.

#### **Method Two**

## Follow these steps to enter a new allergy using the second of the two methods mentioned above:

1. Click to select a causative agent listed in the Allergies/Adverse Reactions pane. CPRS displays a dialog that includes details about the allergy or adverse reaction associated with the selected causative agent. The dialog also includes four buttons.



- 2. Click the Add New button. CPRS displays the Allergy Reactant Lookup dialog.
- 3. Follow steps 4 through 18 of the instructions for entering allergies using the first method. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter A (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If you click the word *Allergies* in the Postings pane, CPRS displays selected information about all of the patient's allergies or adverse reactions, including the allergy or adverse reaction you just entered.

## **Entering No-Known-Allergies Assessments**

You can enter no-known-allergies (NKA) assessments for patients who have no active allergies by taking the following steps:

- 1. Right-click within the Allergies/Adverse Reactions pane.
- 2. From this menu, select Mark patient as having No Known Allergies (NKA). CPRS displays the No Known Allergies dialog.



**Note:** CPRS activates The Mark patient as having No Known Allergies (NKA) menu selection only for patients who have no active allergies. When patients have active allergies, CPRS deactivates this selection.

3. Click **OK**.

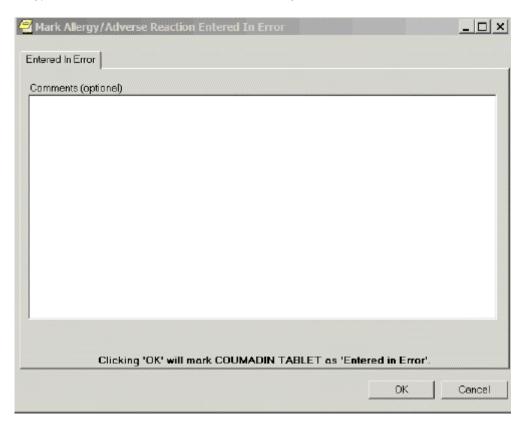
## Marking Allergies as Entered in Error

CPRS offers two methods for marking allergies as having been entered in error:

#### Method One

#### Follow these steps to use the first method:

- 1. In the Allergies/Adverse Reactions pane, place your mouse pointer over an erroneously entered causative agent and right-click to display a menu.
- 2. From this menu, select Mark selected allergy as entered in error. CPRS displays the **Mark** Allergy/Adverse Reaction Entered In Error dialog.



3. If your site has enabled the *Comments* feature, you may (optionally) type comments in the Comments (optional) text box.

**Note:** If your site has not enabled the *Comments* feature, CPRS disables the dialog, which in this case is named Comments (disabled).

- 4. Click **OK**. CPRS displays an Are you Sure? dialog.
- 5. If you are sure the causative agent was entered in error, click Yes. CPRS removes the causative agent from the Allergies/Adverse Reactions pane and from the list of allergies it displays when you click *Allergies* in the Postings pane.

**Note:** CPRS also generates a Progress Note when an allergy is marked "Entered in Error". When this note is signed by the user who marked the allergy as entered

in error or by an administrative update user, the note will be viewable by all CPRS users.

#### **Method Two**

#### Take the following steps to use the second method:

- 1. Click a causative agent (or highlight using the Tab and arrow keys and press <Enter>) that appears in the Allergies/Adverse Reactions pane. CPRS displays a dialog that contains detailed information about the allergy or adverse reaction. This dialog includes four buttons.
- 2. Click the Entered in Error button. CPRS displays the Mark Allergy/Adverse Reaction Entered In Error dialog.
- 3. If your site has enabled the *Comments* feature, you may (optionally) type comments in the Comments (optional) dialog.
- 4. Click OK. CPRS displays an Are you Sure? dialog.
- 5. If you are sure the causative agent was entered in error, click **Yes.** CPRS removes the causative agent from the Allergies/Adverse Reactions pane and from the list of allergies it displays when you click *Allergies* in the Postings pane.

**Note:** CPRS also generates a Progress Note when an allergy is marked "Entered in Error". When this note is signed by the user who marked the allergy as entered in error or by an administrative update user, the note will be viewable by all CPRS users.

## **Allergy Detail changes**

When you look at the detail of an allergy, you may see updates based on the VETS push.

Sample of detail listed below:

Causative agent: PROPYL PARABEN
Nature of Reaction: Adverse Reaction

Signs/symptoms: ECG: EXTRASYSTOLE

PAIN IN EYE

MYOCARDIAL INFARCTION

MUSCLE WEAKNESS

AKATHISIA

SERUM AMYLASE RAISED WEIGHT GAIN FINDING WEAKNESS PRESENT

Drug Classes: MULTIVITAMINS

Originator: CPRSTESTER, TWO (BAY PINES TEST LAB)

Originated: Jun 07, 2005@18:06 Obs dates/severity: JUN 07, 2005 SEVERE

Verified: <auto-verified>

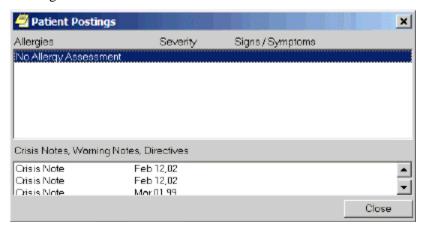
Observed/Historical: Observed

## **Reviewing and Creating Postings**

Postings contain critical patient-related information that hospital staffs need to be aware of. The Postings button is visible on all tabs of the CPRS GUI window and is always located in the upper right corner of the window.

To view a posting using the Postings (CWAD) button, follow these steps:

1. Click the Postings button (available from any tab). CPRS displays the *Patient Postings* dialog.



2. From the *Patient Postings* dialog, click to select the particular posting in which you are interested.

#### To view the posting from the Cover Sheet, follow these steps:

- 3. On the Cover Sheet tab, click on a specific posting that appears in the Postings pane to display the details.
- 4. When finished, click Close.

## **Entering Allergies from the Orders Tab**

Although allergies and adverse reactions are not orders and CPRS does not display them on the **Orders** tab, you can enter allergies and adverse reactions from the **Orders** tab. You can also enter allergies from the **Cover Sheet** tab. (See "Entering Allergies" in the Assessing, Entering, and Reviewing Allergies/Adverse Reactions" section of this manual.)

#### **Entering New Allergies**

To enter allergies or adverse reactions from the **Orders** tab, take the following steps:

1. Click the Orders tab.

2. Select Allergies from the Write Orders pane. The Allergy Reactant Lookup dialog appears.

**Note**: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the Location for Current Activities dialog appears before the Allergy Reactant Lookup dialog appears. You must complete the Location for Current Activities dialog before proceeding.

- 3. Type the causative agent in the search field. (You must enter the first three letters (minimum) of the agent's name.)
- 4. Click Search.

Matching agents appear in the Select from one of the following items pane. If the causative agent you typed does not match any of the agents currently available for your site, CPRS displays the Causative Agent Not On File dialog, from which you can select one of the following options:

**Note:** The patient's chart will not be updated unless you choose a causative agent that is on file.

- a. Yes: Use this option to request that the causative agent be added for your site. When you click Yes, CPRS displays the Enter Optional Comments dialog, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or whether you observed these symptoms firsthand. After you type your comments, click Continue. CPRS then sends to members of your site's GMRA Request New Reactant mail group a message that includes the following items:
  - The causative agent you attempted to enter
  - The name of the patient for whom you attempted to make this entry
  - Your name, title, and contact information
  - Your comments

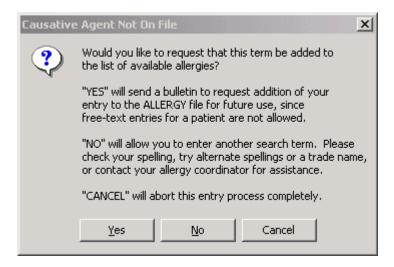
Members of your site's GMRA Request New Reactant mail group will review this message and, if appropriate, request (through NTRT) that the causative agent be added to the national ALLERGIES REACTANT file.

**Note:** If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:



b.No: Use this option if you want to try an alternate spelling or trade name for your causative agent, or if you want to type another causative agent.

c. Cancel: Use this option if you want to cancel your allergy order.

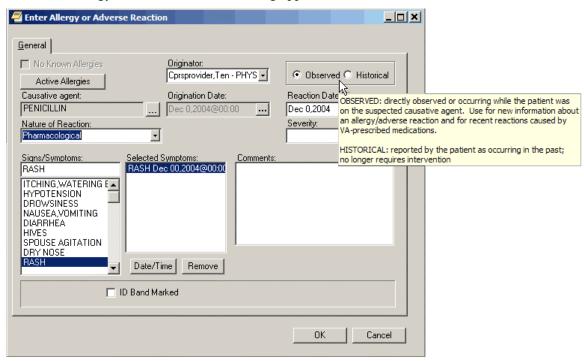


5. If the causative agent you typed matches an agent that is currently available for your site, select the agent. (Click + to expand a heading.)

**Note:** With CPRS GUI 24 or later, you may not add free-text causative agents. If you select an item under the "Add new free-text allergy" heading, CPRS displays the Causative Agent Not On File dialog. (See Step 4 above.)

6. Click **OK**.

The Enter Allergy or Adverse Reaction dialog appears.



**Note**: You can view a patient's current allergies or adverse reactions by clicking the Active Allergies button.

7. Using the Originator box, select an originator.

8. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (When you point your mouse at either of these buttons, CPRS displays a hover hint explaining the observed and historical options.)

**Note:** CPRS does not allow you to select future dates for observed allergy/adverse

reaction entries.

**Note:** When you select Observed for a drug reaction, CPRS generates a Progress Note.

Once this note is signed by the user entering the allergy or by an administrative

update user, the note will be viewable by all users.

9. Select the Nature of Reaction (Allergy, Pharmacological, or Unknown).

The Nature of Reaction (also known as mechanism)can be Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter.

**Note:** Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

10. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity text box is not visible for historical allergies. When the Severity box is visible, CPRS displays a ? button next to it. If you click this button, CPRS displays text that provides information about available severity selections.)

Note: CPRS does not allow you to enter future dates for observed reactions.

- 11. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.
- 12. To associate a date and time with a symptom (optional), click to select the symptom in the Selected Symptoms pane.
- 13. Click the Date/Time button located below the Selected Symptoms pane. CPRS displays the Select Date/Time dialog, from which you can select the date and time that the symptom first appeared.

**Note:** If you mistakenly entered a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the **Selected Symptoms** pane and click the **Remove** button located beneath the pane.

- 14. Type comments for the allergy in the Comments box.
- 15. If you have marked the allergy or adverse reaction on the patient's identification (ID) band (or if you know someone else has), select the ID Band Marked check box.

**Note:** CPRS activates the ID Band Marked check box only for inpatients and then only if your site's IRM staff has set a parameter indicating your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do *not* select activated ID Band Marked check box, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

#### 16. Click OK.

Although CPRS does not display allergy-related assessments on the Orders tab, you can also enter an assessment of no known allergies (NKA) from the Orders tab.

## **Entering No Known Allergies**

To enter a no-known allergies assessment from the Orders tab, follow these steps:

- 1. Click the Orders tab.
- 2. Select Allergies from the Write Orders pane. The Allergy Reactant Lookup dialog appears.

Note: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the Location for Current Activities dialog appears before the Allergy Reactant Lookup dialog appears. You must complete the Location for Current Activities dialog before proceeding.

- 3. Select the No Known Allergies checkbox in the lower portion of the dialog box.
- 4. Click OK.

**Note**: You can also enter a no-known-allergies assessment from the Cover Sheet tab.

## **Glossary**

Adverse Reaction Only Adverse Reaction Tracking

Adverse Reaction Any condition precipitated by a drug that requires patient

treatment, admission or transfer; prompts a specialty consultation; or causes injury or death. Every allergy is an adverse reaction, but every adverse reaction is not an allergy. Something that is an adverse reaction but not an allergy.

The software package that stores and reports the patient

allergy or adverse reaction data.

Allergy A state of hypersensitivity induced by exposure to a certain

agent

Application A system of computer programs and files that have been

specifically developed to meet the requirements of a user or group of users. Examples of VistA applications are the MAS

The name of the item that caused the patient to have a reaction

and Nursing modules

Application Coordinator The person responsible for implementing a set of computer

programs (application package) developed to support a specific functional area such as Nursing, MAS, etc.

ART See Adverse Reaction Tracking.

Causative Agent

(e.g., penicillin).

Date/Time Chart Marked

In ART, this field indicates when the patient's chart has been

marked to indicate this allergy or adverse reaction.

Date/Time ID Band Marked In ART, this field indicates when the patient ID band or

bracelet has been marked to indicate this allergy or adverse

reaction

Date/Time MD Notified A field in ART that indicates when the primary physician has

been alerted about a patient allergy or adverse reaction.

Dechallenge Discontinuation/removal of allergen.

GMR Allergies File A file of allergies/adverse reactions that are used by ART. The

file number is 120.82.

GMRA MARK CHART bulletin Warning that is generated when Date/Time Chart Marked

field is left blank. This warning indicates that someone has to record this allergy or adverse reaction in the patient's chart.

GMRA MARK CHART mail group

This is the group of people who are charged with the

responsibility to see that all data entered into ART gets

recorded in the patient's chart.

GMRA VERIFY ALLERGY bulletin Warning that an allergy or adverse reaction has been signed off (completed) by the originator and that it is ready for the

verification process.

GMRA-VERIFY ALLERGY security Should

key

Ingredient file

Historical

Should be given to all verifiers in ART. Allows a verifier

access to the verification process

An allergy that has been stated by some source versus one that

has actually been witnessed by some personnel at this facility.

A file (#50.416) that contains generic drugs that are

components of various drug products.

Likelihood A measure of the probability that an allergy or adverse

reaction was the cause of the patient problems indicated by the

signs/symptoms. This field is calculated via an FDA algorithm
Local Drug File

The list of medications used at a particular VA facility. This

file is also sent out by the VistA Pharmacy developers. The

file number is 50.

Mechanism In the context of ART, this is an indicator of whether the data

for a patient is an adverse reaction only, or an allergy.

NTRT New Term Rapid Turnaround. Requests for new terms will be

made via the NTRT process. If approved, the new term will be

sent to all sites for inclusion in file 120.82 or 120.83.

National Drug File This file is a list of drug products available, which includes

specific information for each product. Information included for the products are trade name, NDC number, manufacturer, VA Drug Class code, dosage form, route of administration, strength and units, ingredients, ingredient strength and units, package code, package size, package type, VA product name

and VA generic name.

Observed An allergy or adverse reaction that has actually been

witnessed by some personnel at this facility.

Patient Allergies File The file where the patient allergy/adverse reaction data is

stored in ART. The file number of this file is 120.8.

Reintroduction of allergen after dechallenge.

Severity This is an index of how the allergy/adverse reaction affected

the patient.

Sign/Symptom Something that could be subjectively or objectively measured

that indicates an allergy or adverse reaction.

Sign/Symptoms File A list of signs/symptoms that can be selected for a patient

allergy or adverse reaction. The file number is 120.83.

Top Ten Signs/Symptoms A site-configurable set of indicators of an allergy or adverse

reaction that is used to expedite data entry of these indicators. This is some lab test or drug intervention that was performed

Treatment This is some lab test or drug intervention that was perfo

as a result of an allergy or adverse reaction.

True Allergy Something that is an allergy, which implies that it is also an

adverse reaction.

VA Drug Classification System file A file (#50.605) that contains the VA Drug Classification

codes and their descriptions. Each drug product in the

National Drug file is assigned a primary code, which is part of the information stored for each drug product in the National

Drug file.

Verification The process of reviewing and approving the data entered by

some clinical user. This process is done by a verifier.

Verifier A person who has the GMRA-VERIFY ALLERGY security

key. This person can perform verification of patient data in

ART.

Rechallenge

# **Appendix 1: National GMR Allergies File** (120.82) Entries

ADHESIVE TAPE

ALCOHOL

ANIMAL HAIR

ANISE OIL

ANTIRABIES SERUM

ASCORBIC ACID

**ASPARTAME** 

**ASPIRIN** 

AUROTHIOGLUCOSE (SESAME OIL)

**BANANA** 

**BCG VACCINE** 

BENZALKONIUM CHLORIDE

**BISMUTH SUBSALICYLATE** 

**BOTULISM ANTITOXIN** 

**BROAD BEANS** 

**BUTTERSCOTCH FLAVORING** 

CAFFEINE

CALCITONIN, SALMON

**CAPSAICIN** 

**CARROTS** 

**CETYLPYRIDINIUM** 

**CHEESE** 

**CHICKEN** 

**CHOCOLATE** 

CINNAMON OIL

CITRATED CAFFEINE

**CITRUS** 

**CLOVE OIL** 

COCOA

COD LIVER OIL

**CORN** 

COTTONSEED OIL

DAIRY PRODUCTS

DAVE'S ENTRY

DIGOXIN IMMUNE FAB (OVINE)

DIPHTHERIA ANTITOXIN, EQUINE

DIPHTHERIA TOXOID

**DUST** 

**EGGS** 

ESTRADIOL CYPIONATE

FD&CBLUE#2

FD&CGREEN#6

F D & C RED #3

F D & C RED #40

FD & CRED #40 LAKE

FD&CYELLOW#6

F D & C YELLOW #6 LAKE

**FAT EMULSIONS** 

**FIGS** 

**FISH** 

FLUPHENAZINE DECANOATE

FOOD PRESERVATIVES

FOOD STARCH, MODIFIED

**GELATIN** 

**GOLD SODIUM THIOMALATE** 

HEPARIN SODIUM (BEEF LUNG)

HEPARIN SODIUM (PORK)

HERRING

HORSE SERUM

**INSULIN** 

**IODINE** 

**IRON FILLINGS** 

**LACTOSE** 

LICORICE

MALTOSE

METHYL SALICYLATE

METHYLCELLULOSE

**MILK** 

**MOLD** 

MONOSODIUM GLUTAMATE

NAFARELIN ACETATE

NANDROLONE, ETC

**NUTS** 

OTHER ALLERGY/ADVERSE REACTION

PARA-AMINOBENZOIC ACID

**PARABEN** 

**PEACHES** 

PEANUT OIL

**PEPPERMINT** 

PINEAPPLE

**PLUMS** 

**POLLEN** 

**POLYSORBATE** 

**PORK** 

POTASSIUM IODIDE

**POTATO** 

**POULTRY** 

POVIDONE IODINE

**PSYLLIUM** 

RABIES IMMUNE GLOBULIN

RED FOOD DYE

**SACCHARIN** 

SAFFLOWER OIL

SALICYLAMIDE

SALICYLIC ACID

SESAME OIL

SHELL FISH

**SHRIMP** 

**SOY BEANS** 

**SOY SAUCE** 

**STRAWBERRIES** 

**SULFITES** 

SUNFLOWER OIL

TARTARIC ACID

**TESTOSTERONE** 

TOMATO VANILLA VASOPRESSIN TANNATE (IN OIL) WHEAT YEAST YOGURT

# **Appendix 2: National Sign/Symptoms** (120.83) File Entries

	Reaction Name	Properties
1	ABDOMINAL BLOATING	Synonym
2	ABDOMINAL CRAMPS	Synonym
3	ABDOMINAL DISCOMFORT	Synonym
4	ABDOMINAL PAIN	Synonym
		GASTROINTESTINAL PAIN
		GI PAIN
5	ABNORMAL ECG	Synonym
		ECG CHANGES
6	ABNORMAL SEXUAL FUNCTION	Synonym
		SEXUAL DYSFUNCTION
7	ABSCESS	Synonym
8	ACIDOSIS	Synonym
9	ACNE	Synonym
10	ACUTE INTERSTITIAL NEPHRITIS	Synonym
		AIN
11	ACUTE RENAL FAILURE SYNDROME	Synonym
12	ACUTE RENAL IMPAIRMENT	Synonym
		ACUTE RENAL INSUFFICIENCY
13	ACUTE RESPIRATORY DISTRESS	Synonym
14	ACUTE TUBULAR NECROSIS	Synonym
		ATN
15	AGGRESSIVE BEHAVIOR	Synonym
		AGGRESSION
16	AGRANULOCYTOSIS	Synonym
17	AKATHISIA	Synonym
		MOTOR RESTLESSNESS
		RESTLESSNESS
18	AKINESIA	Synonym
40	ALIZALINE BUOGRUATAGE BAIGER	0
19	ALKALINE PHOSPHATASE RAISED	Synonym
	ALT (OODT) LEVEL ADMODAAA	ALK, ELEVATED
20	ALT (SGPT) LEVEL ABNORMAL	Synonym
-		ALT, ELEVATED
		SGPT, ELEVATED
21	AMNESIA	Synonym
		FORGETFULNESS

		LOSS OF MEMORY
22	ANAPHYLAXIS	Synonym
		ANAPHYLACTIC REACTION
		ANAPHYLACTIC SHOCK
23	ANEMIA	Synonym
24	ANGINA	Synonym
25	ANGIOEDEMA	Synonym
26	ANGIONEUROTIC EDEMA OF LARYNX	Synonym
		EDEMA OF LARYNX
27	ANKLE EDEMA	Synonym
		EDEMA OF ANKLES
		EDEMA OF THE ANKLE
28	ANOREXIA	Synonym
29	ANTIBIOTIC-ASSOCIATED DIARRHEA	Synonym
30	ANURIA	Synonym
31	ANXIETY	Synonym
32	APHTHOUS ULCERATION	
		APHTHOUS ULCERS
33	APNEA	Synonym
34	APTYALISM	Synonym
		DRY MOUTH
35	ARTHRITIS	Synonym
36	ASCITES	Synonym
		HYDROPERITONEUM
37	ASEPTIC MENINGITIS	Synonym
		STERILE MENINGITIS
38	AST (SGOT) LEVEL ABNORMAL	Synonym
		AST, ELEVATED
		SGOT, ELEVATED
39	ASTHENIA	Synonym
40	ASTHMA	Synonym
41	ATAXIA	Synonym
42	ATHETOSIS	Synonym
43	ATRIAL FIBRILLATION	Synonym
44	ATRIAL FLUTTER	Synonym
45	AV JUNCTIONAL RHYTHM	Synonym
		JUNCTIONAL RHYTHM
46	BLEEDING	Synonym
47	BLEEDING SKIN	Synonym
		SKIN BLEEDING
48	BLISTER	Synonym
		BULLA

49	BLOOD IN URINE	Synonym
		HEMATURIA
50	BONE MARROW DEPRESSION	Synonym
		BONE MARROW SUPPRESSION
51	BRADYCARDIA	Synonym
		BRADYARRHYTHMIA
		DECREASED HEART RATE
52	BRADYPNEA	Synonym
53	BRONCHOSPASM	Synonym
		BRONCHOCONSTRICTION
54	BUNDLE BRANCH BLOCK	Synonym
55	BURNING SENSATION	Synonym
		BURNING
56	CANDIDIASIS OF MOUTH	Synonym
		ORAL THRUSH
		THRUSH
57	CARDIAC ARREST	Synonym
		ASYSTOLE
58	CEREBRAL HEMORRHAGE	Synonym
59	CEREBROVASCULAR ACCIDENT	Synonym
		CVA
		STROKE
60	CHANGE IN BEHAVIOR	Synonym
		BEHAVIORAL CHANGE
61	CHEST PAIN	Synonym
62	CHILL	Synonym
63	COMA	Synonym
	CONDUCTION DISORDER OF THE HEART	Synonym
65	CONGESTION OF THROAT	Synonym
		SWELLING OF THROAT
66	CONGESTIVE HEART FAILURE	Synonym
		CHF
67	CONJUNCTIVAL EDEMA	Synonym
		CONJUNCTIVAL CONGESTION
68	CONJUNCTIVITIS	Synonym
		PINK EYE
	CONSTIPATION	Synonym
70	CONSTRICTED PUPIL	Synonym
		MIOSIS
71	CONSTRICTION IN THROAT	Synonym
		THROAT CONSTRICTION
72	CONTACT DERMATITIS	Synonym
		DERMATITIS, CONTACT

73	COORDINATION PROBLEM	Synonym
		DISCOORDINATION
		DISTURBED COORDINATION
		INCOORDINATION
74	COUGH	Synonym
		COUGHING
75	CRAMP	Synonym
76	CUTANEOUS ERUPTION	Synonym
		ERUPTION
		RASH
77	CYANOSIS	Synonym
		SKIN CYANOSIS
78	DEAFNESS SYMPTOM	Synonym
		DEAFNESS
79	DECREASED RENAL FUNCTION	Synonym
	DEHYDRATED	Synonym
81	DELAY WHEN STARTING TO PASS URINE	Synonym
		Synonym
82	DELIRIUM	Synonym CLOUDING OF
		COUDING OF CONSCIOUSNESS
		CONFUSION
83	DELUSIONS	Synonym
	DEMENTIA	Synonym
	DEPRESSION	Synonym
	DERMATITIS	Synonym
	DIARRHEA	Synonym
	DIFFICULTY SPEAKING	Synonym
	DIPLOPIA	Synonym
	2011/	DOUBLE VISION
90	DISCOLORATION OF SKIN	Synonym
	Diede Zeita tillett ei eitat	SKIN DISCOLORATION
91	DISINHIBITION	Synonym
	DISORIENTED	Synonym
	BIOGRAPHE	DISORIENTATED
		DISORIENTATION
93	DIURESIS	Synonym
55	DIGITE DIG	UNCONTROLLED DIURESIS
94	DIVERTICULITIS	Synonym
	DIZZINESS	Synonym
	DREAM ANXIETY DISORDER	Synonym
JU	DREAM ANAIETT DIOURDER	Зунонуш
		NIGHTMARE

97	DREAM DISORDER	Synonym
		DREAMING, INCREASED
98	DROWSY	Synonym
		DROWSINESS
		SOMNOLENCE
99	DRUG-INDUCED MYOPATHY	Synonym
100	DRY SKIN	Synonym
101	DUODENAL ULCER DISEASE	Synonym
		ULCER, DUODENAL
102	DYSKINESIA	Synonym
103	DYSPNEA	Synonym
		BREATHLESSNESS
		DIFFICULTY BREATHING
		SHORTNESS OF BREATH
		SOB
104	DYSTHYMIA	Synonym
105	DYSTONIA	Synonym
106	DYSURIA	Synonym
107	ECCHYMOSIS	Synonym
108	ECG: EXTRASYSTOLE	Synonym
		EXTRASYSTOLE
109	ECZEMA	Synonym
110	EDEMA	Synonym
111	EDEMA OF ARM	Synonym
		EDEMA OF THE ARM
112	EDEMA OF LEG	Synonym
		EDEMA OF THE LEG
113	EDEMA OF TONGUE	Synonym
		EDEMA OF THE TONGUE
114	EDEMA, GENERALIZED	Synonym
115	ELEVATED BLOOD PRESSURE	Synonym
116	ELEVATED CREATINE KINASE	Synonym
117	ENGORGEMENT OF BREASTS	Synonym
		BREAST ENGORGEMENT
118	EPISTAXIS	Synonym
119	ERYTHEMA	Synonym
		RED SKIN
120	ERYTHROCYTOSIS	Synonym
		POLYCYTHEMIA
121	EUPHORIA	Synonym
122	EXCESSIVE SALIVATION	Synonym
		DROOLING
		PTYALISM

123 EXCESSIVE SWEATING	Synonym
	DIAPHORESIS
124 EXCESSIVE TEAR PRODUCTION	Synonym
	EPIPHORA
	WATERING EYES
125 EXFOLIATIVE DERMATITIS	Synonym
	DERMATITIS
126 EXTRAPYRAMIDAL SIGN	Synonym
127 EYE SWELLING	Synonym
	SWELLING OF EYES
128 FACE GOES RED	Synonym
	FLUSHING
129 FACIAL GRIMACING	Synonym
	FACIAL DYSKINESIA
130 FACIAL SWELLING	Synonym
131 FATIGUE	Synonym
	EXHAUSTION
	TIREDNESS
132 FEELING AGITATED	Synonym
	AGITATION
133 FEELING FAINT	Synonym
	FAINTNESS
	PRESYNCOPE
134 FEELING INTOXICATED	Synonym
135 FEELING IRRITABLE	Synonym
	IRRITABILITY
136 FEELS WARM	Synonym
	FEELING OF WARMTH
137 FEVER	Synonym
138 FLATULENCE, ERUCTATION AND GAS PAIN	Synonym
139 FURUNCLE OF SKIN	Synonym
140 GALACTORRHEA	Synonym
THO GALACTORRILLA	Cynonym
141 GAMMA GLUTAMYL TRANSFERASE RAISED	Synonym
	GGT, ELEVATED
142 GASTRIC ULCER WITH HEMORRHAGE	Synonym
	BLEEDING GASTRIC ULCER
143 GASTROESOPHAGEAL REFLUX DISEASE	Synonym
	REFLUX
144 GASTROINTESTINAL HEMORRHAGE	Synonym
	GI BLEED
145 GENERALIZED ACHES AND PAINS	Synonym

	GENERALIZED PAIN
	PAIN, GENERALIZED
146 GENERALIZED RASH	Synonym
147 GLAUCOMA	Synonym
148 GOUT	Synonym
149 GRAND MAL EPILEPSY	Synonym
150 GRAND MAL STATUS	Synonym
151 GYNECOMASTIA	Synonym
152 HAIR ABSENT	Synonym
TOD IN MICHIGAN	ALOPECIA
153 HALLUCINATIONS	Synonym
154 HAZY VISION	Synonym
155 HEADACHE	Synonym
156 HEARING LOSS	Synonym
157 HEART BLOCK	Synonym
158 HEARTBURN	Synonym
TOOTEANTBONN	PYROSIS
159 HEMATEMESIS	Synonym
160 HEMOPTYSIS	Synonym
161 HEMORRHOIDS	Synonym
TOTILLIONNITOIDS	Syllollylli
162 HEPARIN INDUCED THROMBOCYTOPENIA	Synonym
163 HEPATOTOXICITY	Synonym
164 HYPERACTIVE BEHAVIOR	Synonym
	HYPERACTIVITY
165 HYPERGLYCEMIA	Synonym
166 HYPERKALEMIA	Synonym
167 HYPERSENSITIVITY	Synonym
168 HYPERTROPHY OF BREAST	Synonym
169 HYPOGLYCEMIA	Synonym
170 HYPOKALEMIA	Synonym
171 HYPOMANIA	Synonym
172 HYPONATREMIA	Synonym
173 HYPOTHERMIA	Synonym
	LOW BODY TEMPERATURE
174 IMPOTENCE	Synonym
175 INAPPROPRIATE ERECTION	Synonym
176 INCONTINENCE OF FECES	Synonym
	FECAL INCONTINENCE
177 INCREASED APPETITE	Synonym
178 INCREASED BILIRUBIN LEVEL	Synonym
	BILIRUBIN LEVEL, INCREASED
179 INCREASED BODY TEMPERATURE	Synonym

		BODY TEMPERATURE, INCREASED
		TEMPERATURE, INCREASED
180	INCREASED FREQUENCY OF URINATION	Synonym
		URINARY FREQUENCY, INCREASED
181	INCREASED LIBIDO	Synonym
		LIBIDO, INCREASED
182	INDIGESTION	Synonym
		DYSPEPSIA
183	INFLAMMATORY DISEASE OF LIVER	Synonym
		HEPATITIS
184	INFLUENZA-LIKE ILLNESS	Synonym
		FLU-LIKE SYMPTOMS
185	INHIBITED ORGASM	Synonym
		ORGASM, INHIBITED
186	INR RAISED	Synonym
		INR, ELEVATED
187	INSOMNIA	Synonym
		SLEEPLESSNESS
188	IRREGULAR HEART RATE	Synonym
		ARRHYTHMIA
		CARDIAC ARRHYTHMIA
		CARDIAC DYSRRHYTHMIA
		HEART ARRHYTHMIA
189	IRRITATION OF PENIS	Synonym
		PENILE IRRITATION
190	ITCHING OF EYE	Synonym
191	JAUNDICE	Synonym
		ICTERUS
192	JOINT PAIN	Synonym
		ARTHRALGIA
		PAIN, JOINT
193	JOINT SWELLING	Synonym
		SWELLING OF JOINTS
194	LABYRINTHITIS	Synonym
	LARYNGEAL SPASM	Synonym
		LARYNGOSPASM
196	LEG CRAMP	Synonym
	LEG SWELLING	Synonym
	-	LEGS, SWELLING
		SWELLING OF LEGS
		SWOLLEN LEGS
198	LETHARGY	Synonym

199	LEUKOCYTOSIS	Synonym
	LEUKOPENIA	Synonym
		DECREASED WBC
201	LIP SWELLING	Synonym
		SWELLING OF LIPS
202	LITHIUM LEVEL HIGH - TOXIC	Synonym
	ETTHOM ELVELTHOTT FORTO	LITHIUM TOXICITY
203	LIVER ENZYMES ABNORMAL	Synonym
		LFT, ELEVATION
204	LONG QT SYNDROME	Synonym
	LOSS OF APPETITE	Synonym
		DECREASED APPETITE
206	LOSS OF SENSE OF SMELL	Synonym
		ANOSMIA
207	LOW BACK PAIN	Synonym
	LOW BLOOD PRESSURE	Synonym
		HYPOTENSION
209	LYMPHADENOPATHY	Synonym
	MALAISE	Synonym
	MALE ERECTILE DISORDER	Synonym
	WINEE ENEOTIEE BIOONDEN	ERECTILE DYSFUNCTION
		IMPAIRMENT OF ERECTION
212	MELENA	Synonym
		STOOLS, BLACK OR TARRY
213	MENOPAUSAL FLUSHING	Synonym
		HOT FLASHES
214	MIGRAINE	Synonym
215	MOOD SWINGS	Synonym
	MUSCLE PAIN	Synonym
		MYALGIA
217	MUSCLE WEAKNESS	Synonym
218	MYOCARDIAL INFARCTION	Synonym
	MYOSITIS	Synonym
		Synonym
220	NASAL CONGESTION	Synonym
		CONGESTION, NASAL
221	NASAL DISCHARGE	Synonym
		RHINORRHEA
222	NASAL MUCOSA DRY	Synonym
		DRY NOSE
223	NAUSEA	Synonym
224	NAUSEA AND VOMITING	Synonym
	NERVOUSNESS	Synonym
	NEUROPATHY	Synonym

227 NEUTROPENIA	Synonym
	NEUTROPHIL COUNT,
	DECREASED
228 NIGHT SWEATS	Synonym
229 NUMBNESS	Synonym
230 OLIGURIA	Synonym
231 OPTIC ATROPHY	Synonym
232 PAIN IN EYE	Synonym
	EYE PAIN
233 PAIN IN LEG	Synonym
	LEG PAIN
234 PAIN OF BREAST	Synonym
	MASTALGIA
	MASTODYNIA
235 PALPITATIONS	Synonym
236 PANCREATITIS	Synonym
237 PANCYTOPENIA	Synonym
238 PAPULAR ERUPTION	Synonym
239 PARESTHESIA	Synonym
240 PARKINSONIAN FEATURES	Synonym
	PARKINSONIAN LIKE
044	SYNDROME
241 PARKINSONISM	Synonym
242 PEPTIC ULCER SYMPTOMS	Synonym
- 12	PEPTIC ULCER
243 PERIPHERAL EDEMA	Synonym
	EDEMA, PERIPHERAL
244 PHARYNGEAL DRYNESS	Synonym
	DRY THROAT
245 PHARYNGEAL SPASM	Synonym
246 PHARYNGITIS	Synonym
247 PHLEBITIS	Synonym
248 PHOTOALLERGIC DERMATITIS	Synonym
	DERMATITIS, PHOTOALLERGIC
249 PHOTOSENSITIVITY	Synonym
250 PHYSICAL AGGRESSION	Synonym
	VIOLENCE
	VIOLENT BEHAVIOR
251 PNEUMONIA	Synonym
252 POISONING BY DIGOXIN	Synonym
	DIGOXIN TOXICITY
	İ
253 POISONING BY DRUG AND/OR MEDICINAL SUBSTANCE	Synonym
253 POISONING BY DRUG AND/OR MEDICINAL SUBSTANCE	Synonym DRUG TOXICITY

		DILANTIN TOXICITY
255 POSTICTAL DE	PRESSION	Synonym
256 POSTURAL DR	OP IN BLOOD PRESSURE	Synonym
		ORTHOSTATIC HYPOTENSION
257 PROLONGED F	PENILE ERECTION	Synonym
258 PROLONGED F	PR INTERVAL	Synonym
		INCREASED PR INTERVAL
		PR INTERVAL, INCREASED
259 PRURITUS		Synonym
		ITCHING
260 PSYCHOMOTO	R AGITATION	Synonym
261 PSYCHOSIS		Synonym
262 PSYCHOTIC DI	SORDER	Synonym
		PSYCHOSIS
263 PTOSIS OF EY	ELID	Synonym
264 PTOSIS PRESE	ENT	Synonym
265 PULMONARY E	OSINOPHILIA	Synonym
266 PURPURIC RA	SH	Synonym
267 RAISED INTRA	OCULAR PRESSURE	Synonym
		GLAUCOMA
268 Reactions		Synonym
269 RECTAL HEMO	RRHAGE	Synonym
		BLEEDING, RECTAL
270 REDUCED LIBI	DO	Synonym
		LIBIDO, DECREASED
271 RENAL AZOTE	MIA	Synonym
		AZOTEMIA
272 RENAL FAILUR	E SYNDROME	Synonym
273 RENAL IMPAIR	MENT	Synonym
		RENAL FUNCTION IMPAIRED
		RENAL INSUFFICIENCY
274 RESPIRATORY	ARREST	Synonym
275 RESPIRATORY	CRACKLES	Synonym
		RALES
276 RESPIRATORY	DISTRESS	Synonym
277 RETENTION O	URINE	Synonym
		URINARY RETENTION
278 RETROGRADE	EJACULATION	Synonym
279 RHABDOMYOL		Synonym
280 RHINITIS		Synonym
281 RIGOR		Synonym
		RIGORS
282 SEDATED		Synonym

		SEDATION
283	SEIZURE	Synonym
	SELF-DEPRECIATION	Synonym
	SEROTONIN SYNDROME	Synonym
200	SEROTOMIN STRUKOWE	Synonym
286	SEROTONIN WITHDRAWAL SYNDROME	Synonym
287	SERUM AMYLASE RAISED	Synonym
		AMYLASE, ELEVATED
288	SERUM CREATININE RAISED	Synonym
		ELEVATED SERUM CREATININE
289	SERUM SICKNESS	Synonym
290	SHOCK	Synonym
291	SINUS BRADYCARDIA	Synonym
292	SKIN LESION	Synonym
293	SNEEZING	Synonym
294	SORE THROAT	Synonym
295	SPASMODIC MOVEMENT	Synonym
		JERKING
		TWITCHING
296	SPASTICITY	Synonym
		MUSCLE SPASM
297	SPEECH PROBLEM	Synonym
		SPEECH DISORDER
298	S-T CHANGES	Synonym
		ST CHANGES
299	STEVENS-JOHNSON SYNDROME	Synonym
		STEVEN-JOHNSON
300	STOMATITIS	Synonym
301	STUPOR	Synonym
302	SWELLING	Synonym
		SWELLING (NON-SPECIFIC)
303	SWELLING OF ARM	Synonym
		SWOLLEN ARM
304	SWELLING OF ORAL CAVITY STRUCTURE	Synonym
		ORAL EDEMA
	SWELLING OF TONGUE	Synonym
306	SWOLLEN ANKLE	Synonym
_		ANKLE SWELLING
307	SYNCOPE	Synonym
		BLACKED OUT
		FAINTING
		LOSS OF CONSCIOUSNESS
308	TACHYARRHYTHMIA	Synonym

309	TACHYCARDIA	Synonym
	TACHYPNEA	Synonym
311	TASTE SENSE ALTERED	Synonym
	THROAT IRRITATION	Synonym
	THROAT SPASM	Synonym
314	THROMBOCYTOPENIC DISORDER	Synonym
		THROMBOCYTOPENIA
315	TINNITUS	Synonym
		RINGING IN EARS
316	TRANSAMINASE OR LACTIC ACID DEHYDROGENASE RAISED	
		LDH, INCREASED
317	TREMOR	Synonym
		SHAKINESS
318	UNSTEADY GAIT	Synonym
319	UPPER RESPIRATORY TRACT OBSTRUCTION	Synonym
		ACUTE UPPER AIRWAY
		OBSTRUCTION
		AIRWAY OBSTRUCTION
320	UREMIA	Synonym
321	URINARY INCONTINENCE	Synonym
322	URTICARIA	Synonym
		HIVES
323	UVEITIS	Synonym
		UVEA, INFLAMMED
324	VERTIGO	Synonym
325	VESICLES IN SKIN	Synonym
326	VISUAL DISTURBANCE	Synonym
327	VOMITING	Synonym
328	WEAKNESS PRESENT	Synonym
		WEAKNESS
329	WEIGHT GAIN FINDING	Synonym
		WEIGHT GAIN
330	WHEEZING	Synonym

# Appendix 3: CPRS (GUI 25 & 26) Release Notes - ART

#### **PATCH OR\*3\*233**

**Support for Allergy Synonyms** –Allergy synonyms, if present, are now included in the SIGNS/SYMPTOMS selection box. This is included in patch OR\*3\*233, which will be distributed with GMRA patch 23.

### **GUI 26**

- The "Bulletin has been sent" message that CPRS displays after the user requests the addition of a new causative agent now includes the same warning included in the bulletin about that reactant not being added to the patient's record.
- Marking Allergies as Entered in Error Now Controlled by Parameter In CPRS v25, any user could enter new allergies, mark a patient as NKA (no known allergies), and mark allergies entered in error from the cover sheet and the detailed display window. In v.26, the Entered in Error option requires the new parameter OR ALLERGY ENTERED IN ERROR to be enabled for the user. The other options remain open to all users as before.
- Free-Text Signs and Symptoms No Longer Allowed To support of data standardization efforts, developers removed the ability to enter free-text signs/symptoms. Users must now select items from the list of available signs/symptoms.
- Inconsistent Sending of Bulletin for Marked on Chart CPRS always sent the "Marked on Chart" bulletin if the user entered an allergy from the Orders tab. CPRS never sent the bulletin if the user entered the allergy from the Cover Sheet. This inconsistency has been corrected, and CPRS will never send the bulletin when the user enters a new allergy.

### **GUI 25**

The following functionality is available only to sites that have installed OR\*3.0\*195, OR\*3.0\*216, and GMRA\*4.0\*21 Sites that have not installed these patches will continue to receive the ART functionality that exists in CPRS GUI 24.

• Allergies No Longer Entered as Orders (NOIS: SHR-0603-71103) – At sites that have installed the patches listed above, users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file. Patch OR\*3.0\*216 exports a modified order-dialog entry—*GMRAOR ALLERGY*—in the *ORDER DIALOG* file. This entry enables CPRS to interact directly with the Adverse Reaction Tracking (ART) package (i.e., CPRS adds new allergies and adverse reactions directly into the ART package as users submit them.)

With supporting patches OR\*3.0\*216 and GMRA\*4.0\*21, CPRS GUI 25 does not display allergy information on the **Orders** tab. It displays allergy information only on the **Cover Sheet** tab. Nevertheless, users can still enter allergy information from the **Orders** tab by selecting **Allergies** in the **Write Orders** pane. (i.e., users can still go to a familiar place to enter allergies.)

In addition, users can no longer select **OTHER ALLERGY/ADVERSE REACTION** as causative agent, nor can they select **OTHER REACTION** as a sign/symptom. Changes to the ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

If 'type of causative agent' references the field ALLERGY TYPE, the GUI interface doesn't allow the user to enter this information. It is determined internally by the selection made during the Reactant lookup process. "OTHER REACTION" is still selectable from the signs/symptoms list; free text entries of signs/symptoms are allowed.

Also, CPRS now requires users to enter information about the nature of the reaction that they are documenting (Allergy, Pharmacological, or Unknown).

Finally, CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site's *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate—by clicking either its **YES** or **NO** button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was **YES**. In CPRS GUI 25, the default button is **NO**. Furthermore, when users click the system **X** button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

- **Allergy Changes on the Cover Sheet** CPRS now enables users to perform several ART-related actions from the **Cover Sheet** tab—including the following:
- Enter new allergy
- Mark selected allergy as entered in error
- Mark patient as having "No Known Allergies" (NKA)

When users right-click within the **Allergies/Adverse Reactions** pane, CPRS displays a menu offering the three selections listed in the previous paragraph (or a sub-set, depending on the current Allergy information recorded for the patient). When users left click to select one of the allergies listed within the **Allergies/Adverse Reactions** pane, CPRS opens a window that displays details about this allergy-as it always has. However, this window now includes two additional buttons: **Add New** and **Entered in Error**. As the names of these buttons suggest, clicking them enables users to add new allergies and designate the selected allergy as entered in error, respectively. When users mark allergy entries as entered in error, the ART package notifies (via MailMan bulletins) sites' GMRA MARK CHART mail group.

Depending on how sites have configured their *GMR ALLERGIES SITE PARAMETERS* files, the ART package could also send bulletins to one or more of the following mail groups: GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD ALLERGY, and GMRA VERIFY OTHER ALLERGY. In addition, marking an allergy entry as entered in error triggers the Text Integration Utility (TIU) package to generate an Allergy/Adverse Reaction progress note that is sent to the originator to document the erroneous entry. Whether users enter new allergies via the Cover Sheet or Orders tab, CPRS displays an Enter Allergy or Adverse Reaction dialog, through which users enter adverse reactions and allergies directly into the ART package. This dialog includes several changes, including the following changes:

• CPRS no longer allows users to enter future origination dates or future dates for observed allergies; if users attempt to enter future dates for these items, CPRS prevents them from doing so when they click OK to submit their allergy entries

- A new button containing a question mark is associated with the Severity dialog; when users select this button, CPRS displays a text box defining severity selections
- CPRS displays a hover hint when users mouse over the Observed and Historical
  option buttons; a user group (as opposed to OI staff) specified the text of the hoverhint
- When the amount of text in the Comments dialog exceeds its viewing area, CPRS adds a scroll bar to the dialog
- Developers altered the tabbing sequence to more closely match users' expectations
- When an allergy is marked as "Entered in Error," Drug allergy, this action generates
  a Progress Note for the user who marked it as "entered in error" to sign. Once the
  user who marked the allergy as entered in error or an administrative user signs the
  note, all CPRS users can view the note to know that an allergy has been removed
  from the list.
- When an allergy is entered as an "Observed, Drug allergy," this action generates a Progress Note for the user who entered the Allergy/Adverse reaction to sign. Once the user who made the entry or an administrative user signs the note, all CPRS users can view the note.

The **Enter Allergy or Adverse Reaction** dialog also contains a new check box: **ID Band Marked**. If the patients are inpatients and the sites have set the MARK ID BAND parameter in the *GMR ALLERGY SITE PARAMETERS* file to **1** (**YES**), users can select this check box to indicate whether they have marked allergies and adverse reactions on the patient's identification (ID) bands. If users submit an allergy entry without selecting activated **ID Band Marked** check box, the ART package automatically notifies sites' GMRA MARK CHART mail group via a MailMan bulletin. *GMR ALLERGY SITE PARAMETER* file settings also determine to which verification mail groups (GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD ALLERGY, or GMRA VERIFY OTHER ALLERGY) the ART package sends MailMan bulletins when users enter specific combinations of allergy information.

## **Deleting an assessment of NKA**

From within the ART package, it is now possible to delete an assessment of NKA.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the "Does this patient have any known allergies or adverse reactions?" prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

## Examples:

1) Patient who is currently not assessed:

Select PATIENT NAME: **ARTPATIENT,ONE** 1-20-57 456334567
YES MILITARY RETIREE THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :

2) Patient who has been assessed as NKA:

```
Select PATIENT NAME: ARTPATIENT,ONE 1-20-57 456334567
YES MILITARY RETIREE THIS IS A TEST
Does this patient have any known allergies or adverse reactions? : No//
```

At this point, if I enter a ?, I see what my choices are:

```
Choose from:
1 Yes
0 No
```

You may also enter @ to delete a previous NKA assessment and return the patient to a 'not assessed' state. Use this if the NKA assessment was previously incorrectly entered.

Does this patient have any known allergies or adverse reactions? : No//

The information regarding the use of the @ will only show if the patient is currently NKA. If they are not, then it doesn't show.

3) Finally, here's what it looks like when you delete the assessment:

```
Select PATIENT NAME: ARTPATIENT,ONE 1-20-57 456334567 YES MILITARY RETIREE THIS IS A TEST

Does this patient have any known allergies or adverse reactions? : No// @

Assessment deleted.
```